Silvex
Position Document 1/2/3

(U.S.) Environmental Protection Agency
Arlington, VA

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Risk/benefit analysis: qualitative & quantitative risks of a pesticide, value of crop uses, availability of alternative pesticides, exposure to man and environment. Identification of risk reducing regulatory options and proposed Agency action.

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PRELIMINARY DETERMINATION CONCERNING A REBUTTABLE PRESUMPTION AGAINST REGISTRATION OF PESTICIDE PRODUCTS CONTAINING 2-(2,4,5-TRICHLOROPHENOXY PROPIONIC ACID (SILVEX)

NOTICE OF INTENT TO HOLD A HEARING TO DETERMINE WHETHER OR NOT CERTAIN USES OF SILVEX SHOULD BE CANCELLED

NOTICE OF AVAILABILITY OF POSITION DOCUMENT

SILVEX: POSITION DOCUMENT 1/2/3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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July 9, 1979

ENVIRONMENTAL PROTECTION AGENCY

[FRL- OPP-]

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I. INTRODUCTION

On February 28, 1979 the Administrator of the Environmental Protection Agency (EPA) ordered the emergency suspension of the use of two phenoxy herbicides, 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) and 2-(2,4,5-trichlorophenoxy) propionic acid (silvex) on forests, rights-of-way and pastures, and the home and garden, aquatic ditch bank/weed control, and commercial/ornamental turf uses of silvex (suspended uses). (44 FR 15897, March 15, 1979).1/

The emergency suspension orders were based in part on data and information developed for and through the Agency's rebuttable presumption against registration

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1/ Suspension hearings commenced on April 19, 1979, but were discontinued on May 15, 1979 after all registrants withdrew from the hearings. The first prehearing conference for the related cancellation proceedings was held on June 5, 1979; the formal evidentiary hearing will probably begin in the fall.

(RPAR) for pesticide products containing one of these chemicals, 2,4,5-T (43 FR 17116, April 21, 1978). Silvex was included in the suspension orders in part because 2,4,5-T and silvex both contain the contaminant 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), a highly toxic chemical, have comparable uses and correspondingly comparable exposure potential, and pose risk concerns which are similar in many ways.

At the time the suspension orders were issued, silvex was a candidate for a rebuttable presumption against registration (RPAR), but an RPAR had not been issued. However, the RPAR review of 2,4,5-T and the suspension action prompted the Agency to expedite its RPAR review of the use of silvex on rangeland, rice, sugarcane, orchards and non-crop areas[2/] (non-suspended uses). As a result of this expedited review, the Agency has determined that the non-suspended uses of silvex meet the risk criteria for issuance of a rebuttable presumption against registration based on the oncogenic and other chronic or delayed toxic effects risk criteria for issuance of a rebuttable presumption against registration. (40 CFR 162.11(a)(3)).

[2/] The non-crop uses of silvex include use on or around non-crop sites, including fencerows, hedgerows, fences (not otherwise included in suspended uses, e.g, rights of way, pasture); industrial sites or buildings (not otherwise included in suspended uses, e.g., rights-of-way, commercial/ornamental turf); storage areas, waste areas, vacant lots, parking areas.

The Agency has also determined that the criteria for rebutting the presumptions of risks do not appear to be satisfied, and that the risks appear to be greater than the benefits.[3]

Accordingly, the Agency is announcing its determination to initiate proceedings to determine whether or not to cancel or modify the terms and conditions of registration of the non-suspended uses of silvex, pursuant to FIFRA section 6(b)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §§136 et. seq. (FIFRA). As explained in this notice, this action is a preliminary determination at this point, pending external review through submission to and review by the United States Department of Agriculture and the Scientific Advisory Panel, pursuant to FIFRA sections 6(b) and 25(d). The action does not become final until the Agency has reviewed the comments of these reviewers and issued final notices based in part on consideration of these comments.

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[3] Ordinarily, the public phase of the RPAR review of a chemical begins with issuance of a notice of rebuttable presumption in which the Agency presents the data and other information which indicate that the chemical meets or exceeds the risk criteria set out at 40 CFR 162.11(a)(3). The Agency invites registrants and other interested parties to comment on the data and information, and to present information on the benefits of the chemical. The rebuttals to the presumption and the information on benefits are reviewed and a Position Document 2/3 presenting the Agency's review of data relating to risks and benefits is issued to the public, and submitted to the U.S. Department of Agriculture and the Scientific Advisory Panel for review (see section II of this Notice).

In the present case, the Agency has collapsed these procedures into a single action because the data and information indicating that the non-suspended uses of silvex appear to present unreasonable risks to the environment indicate that a decision on these chemicals should be reached as expeditiously as possible. It is in the public interest to consolidate decisionmaking on all uses of 2,4,5-T and silvex in a single legal proceeding. Moreover, since the action is at this point preliminary and subject to revision after consideration of the views and recommendations of the United States Department of Agriculture, pesticide registrants, the Scientific Advisory Panel, and other interested parties, the public review and comment function of the RPAR process is fully satisfied by the procedures outlined in this notice.

In broad summary, the Agency has determined that the non-suspended uses of silvex meet or exceed the risk criteria for issuance of an RPAR set out at 40 CFR 162.11 (a)(3), and that applicable data and information submitted in response to TCDD issues in the 2,4,5-T RPAR do not rebut the presumptions. Therefore, the risks to humans of oncogenic, fetotoxic, and teratogenic effects are of sufficient concern to require the Agency to consider whether offsetting economic, social or environmental benefits exist.

The Agency has considered benefits information which pesticide registrants, the U.S. Department of Agriculture, and other interested parties have provided to the Agency, and has analyzed the economic benefits of the non-suspended uses of silvex. The Agency has weighed risks and benefits together in order to determine whether the risks of each use are warranted by the benefits of the use.

With respect to the non-suspended uses of silvex, the Agency has determined: (1) that these uses appear generally to cause unreasonable adverse effects on the environment, (2) that there are uncertainties in the data relating to the risks and benefits of these uses, (3) that additional data on the risks and benefits of the non-suspended uses of silvex will permit the Agency to determine whether or not to cancel the registrations for these uses, and (4) that such information can best be acquired through a public hearing pursuant to FIFRA Section 6(b)(2).

The remainder of this Notice and the accompanying Position Document set forth in detail the Agency's analysis of data and information relating to the risks and benefits of the non-suspended uses of silvex and the Agency's reasons and factual bases for the regulatory action it is initiating. The Notice is organized into four sections. Section I is this introduction. Section II sets forth a general discussion of the regulatory framework within which this action is taken. Section III sets forth the Agency's preliminary determinations relating to the risks and benefits associated with the non-suspended uses of silvex and initiating the regulatory actions which flow from these determinations. Section IV provides a brief discussion of the procedures which will be followed in implementing the regulatory actions which the Agency is initiating in this Notice.

II. Legal Background

A. General

In order to obtain a registration for a pesticide under FIFRA, a manufacturer must demonstrate that the pesticide satisfies the statutory standard for registration. That standard requires (among other things) that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment" (FIFRA, section 3(c)(5)). "Unreasonable adverse effects on the environment" is defined to mean "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" (FIFRA, section 2(bb)). In effect, this standard requires a finding that the benefits of each use of the pesticide exceed the risks of use, when the pesticide is used in accordance with the terms and conditions of registration, or in accordance with commonly recognized practice. The burden of proving that a pesticide satisfies the registration standard is on the proponents of registration (e.g., registrants, users), and continues as long as the registration remains in effect. Under section 6 of FIFRA, the Administrator is required to cancel the registration of a pesticide or modify the terms and conditions of registration whenever he determines that the pesticide no longer satisfies the statutory standard for registration.

B. The RPAR Process

The Agency created the rebuttable presumption against registration (RPAR) process to facilitate the identification of pesticide uses which may not satisfy the statutory standard for registration and to provide a public, informal procedure for the gathering and evaluation of information about the risks and benefits of these uses. The regulations governing the RPAR process are set forth in the Agency's regulations at 40 CFR 162.11. This section provides that a rebuttable presumption shall arise if a pesticide meets or exceeds any of the risk criteria set out in the regulations. The Agency generally announces that an RPAR has arisen by publishing a notice in the Federal Register. After an RPAR is issued, registrants and other interested persons are invited to review the data upon which the presumption is based and to submit data and information to rebut the presumption. Respondents may rebut the presumption of risk by showing that the Agency's initial determination of risk was in error, or by showing that use of the pesticide is not likely to result in any significant exposure to man or to animals or plants of concern with regard to the adverse effect in question. Further, in addition to submitting evidence to rebut the risk presumption, respondents may submit evidence as to whether the economic, social and environmental benefits of the use of the pesticide subject to the presumption outweigh the risks of use.

The regulations require the Agency to conclude an RPAR by issuing a Notice of Determination in which the Agency states and explains its position on the question of whether the RPAR risk presumptions have been rebutted. If the Agency determines that the presumption is not rebutted, it will then consider information relating to the social, economic and environmental costs and benefits which registrants and other interested persons submitted to the Agency and other benefits information known to the Agency. After weighing of the risks and the benefits of a pesticide's use, the Agency may conclude the RPAR process either by issuing a notice of intent to cancel or deny registration(s), pursuant to FIFRA section 6(b)(1) and 3(d)(1) or by issuing a notice of intent to hold a hearing pursuant to section 6(b)(2) of FIFRA to determine whether the registration(s) should be cancelled or applications for registration(s) denied.

C. Notices of Intent to Cancel or to Hold a Hearing

FIFRA provides two mechanisms for instituting proceedings to cancel pesticides. The Administrator may issue a notice of intent to cancel a pesticide and offer registrants and other affected persons an opportunity to request a hearing. (FIFRA, §6(b)(1)). Alternatively, the Administrator may issue a notice of intent to hold a hearing to determine whether or not the pesticide should be cancelled. (FIFRA, §6(b)(2)).

The judgment of whether to issue a §6(b)(1) or a §6(b)(2) notice is within the sole discretion of the Administrator or his duly designated delegatee. If the Administrator determines that the risks of a pesticide's use appear to outweigh its benefits, he may issue a notice of intent to cancel pursuant to FIFRA section 6(b)(1). If, however, the Administrator's judgment concerning the risks and benefits of a pesticide's use is only tentative, the Administrator may issue a notice under section 6(b)(2) declaring his intention to hold a hearing "to determine whether or not its registration should be cancelled."

D. External Review

FIFRA requires the Agency to submit notices issued pursuant to section 6 to the Secretary of Agriculappropriate steps are taken to make copies of the Position Document available to registrants and other interested persons at the time the decision documents are transmitted for formal external review, through publication of a notice of availability in the Federal Register, and by other means. Registrants and other interested persons will be allowed the same period of time to comment--30 days--that the statute provides for receipt of comments from the Secretary of Agriculture and the Scientific Advisory Panel.

E. Final Notices

The determination to issue a FIFRA section 6 notice is a preliminary determination, pending external review and Agency analysis of comments received. On the basis of these comments, the Agency may withdraw the notice, issue a final notice without modification, or modify the notice, as appropriate.

After complying with these external review requirements and, if the notice is not withdrawn, accomplishing any changes in the contemplated action which are deemed appropriate as a result of any comments received, the Agency implements the desired regulatory action by sending and making public a notice of intent to cancel under FIFRA section 6(b)(1) or a notice of intent to ture with an analysis of the impact of the proposed action on the agricultural economy (FIFRA, Section 6(b)). The Agency is required to submit these documents to the Secretary of Agriculture at least 60 days before making the notice effective by sending it to registrants or making it public. If the Secretary of Agriculture comments, in writing, within 30 days after receiving the notice, the Agency is required to publish the comments and the Administrator's responses to them along with publication of the notice. FIFRA also requires the Administrator to submit section 6 notices, at the same time and under the same procedures as those described above for review by the Secretary of Agriculture, to the Scientific Advisory Panel for comment on the impact of the proposed action on health and the environment. (FIFRA, §25(d)).

Although not required to do so under the statute, the Agency has determined that it is consistent with the general theme of the RPAR process and the Agency's overall policy of open decisionmaking to afford registrants and other interested persons an opportunity to comment on the bases for the proposed action during the time that the proposed action is under review by the Secretary of Agriculture and the Scientific Advisory Panel. Accordingly, hold a hearing under FIFRA section 6(b)(2). If related hearings are in progress, the Agency may move to consolidate proposed FIFRA section 6(b) proceedings with such ongoing FIFRA proceedings. Hearings are governed by the Agency's rules of practice for hearings under FIFRA section 6 [40 CFR 164]. At the end of the hearing, the Administrator issues his final decision regarding cancellation, which may include an order cancelling some or all uses.

III. Determinations and Initiation of Regulatory Action

The Agency has considered information on the risks associated with the non-suspended uses of silvex, including information submitted by registrants and other interested persons in rebuttal of the 2,4,5-T RPAR. The Agency has also considered information on the social, economic, and environmental benefits of the non-suspended uses of silvex, including information submitted by the United States Department of Agriculture. The Agency's assessment of the risks and benefits of the non-suspended uses of silvex, and its conclusions and determinations as to whether any use of silvex appears to cause unreasonable adverse effects on the environment, are set forth in detail in the Position Document accompanying this Notice.

This Position Document is hereby adopted by the Agency as its statement of reasons for the determinations and actions announced in this Notice. For the reasons summarized below and developed in detail in the Position Document, the principal determinations of the Agency with respect to silvex are as follows:

A. Determination on Risks

Data and information summarized in the Position Document indicate that silvex and/or its TCDD contaminant meet or exceed the oncogenic, and other chronic and delayed toxic effects risk criteria at 40 CFR 162.11(a)(3), and that the rangeland, rice, sugarcane, orchard and non-crop area uses of silvex pose risks of these adverse effects to human populations. As the Position Document explains, the Agency has determined that information available to the Agency (including information submitted to rebut these risk criteria for the 2,4,5-T RPAR) is insufficient to lay to rest the Agency's concerns that silvex and/or TCDD pose risks of fetotoxic and teratogenic effects in unborn children, and that TCDD and silvex containing TCDD pose risks of cancer among exposed populations. The Agency has determined that the uses of silvex create opportunities for human exposure to these chemicals and that such exposure appears generally to cause adverse human effects. The Agency has therefore concluded that the oncogenic, fetotoxic and teratogenic risks associated with the non-suspended uses of silvex are of sufficient magnitude to require the Agency to determine whether the non-suspended uses of silvex offer social, economic, or environmental benefits which offset these risks.

B. Determination of Benefits

The uses of silvex which are subject to this notice fall into five categories: range, rice, sugarcane, orchard and non-crop areas. For each of these use categories an estimate of the economic impact of cancellation of silvex was made.[4/] These estimates are intended only as approximations based on available information.[5/] The Agency's analysis of this available information leads to the conclusion that the benefits of silvex for the five categories of uses are approximately as set forth below.

1. Rangeland

a. Pest Infestation and Damage

Approximately 900 million acres of rangeland exist in the United States. Rangeland is used as grazing land for livestock, principally cattle.[6/] A wide variety of

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[4/] It is assumed that 2,4,5-T also would be canceled and unavailable as a substitute for silvex. In view of the virtually identical toxicological characteristics of the two compounds and the similarity of their benefits, it is unlikely that only one of them would be canceled for the uses for which they are alternatives for each other.

[5/] The Agency is continuing to collect and review data relating to the benefits of silvex for range, rice, sugarcane, orchard, and non-crop areas.

[6/] "Rangeland" is defined as land producing forage for animal consumption, harvested by grazing, which is not cultivated, seeded, fertilized, irrigated or treated with pesticides or other such similar practices on an annual basis. Fencerows enclosing range areas are included as part of the range.

herbaceous and woody plants infest rangeland and compete with the desired forage species for nutrients, water, space and light. The most serious problems occur on rangeland in the southwestern U.S.

b. Use of Silvex and Alternatives

(i) Current Use of Silvex

Each year, approximately 150,000 acres of rangeland in the United States are treated with silvex. Silvex is used almost exclusively in the Southwest. The principal pest species which silvex is applied to control are various oak species.

(ii) Non-Chemical Alternatives

Prior to the introduction and wide-scale use of chemical herbicides, various hand and mechanical methods were the exclusive tools for range weed control. These methods have not been entirely replaced by chemical herbicides. However, while hand and mechanical operations can effectively control many of the pests in a reasonably efficient manner, they do not substitute efficiently for aerial chemical treatments when large tracts of infested acreage are involved.

(iii) Chemical Alternatives

Several registered chemical alternatives as well as non-chemical controls not analyzed here are effective against one or more of the various range weeds controlled by silvex. However, these chemicals are either not registered for aerial application or are not as effective as silvex for aerial application. 2,4-D and dicamba can be applied aerially to rangeland, but they are relatively ineffective as foliar sprays. The USDA Assessment Team concluded that there is no effective alternative to silvex for aerial control of oaks.

Since there are no effective alternatives to aerially applied silvex for oak control, the yield effects resulting from cancellation of silvex for range use could be severe on acreage currently treated with silvex. Cancellation would leave users with no aerially applied alternative control on these acres. In some areas, beef yields could fall substantially.

c. Economic Impact of Cancellation of Silvex for Rangeland

User impacts developed by the USDA Assessment Team members are used in this analysis. These estimates were based on available information (both empirical and opinion) and form approximate measures of potential impacts.

Current silvex use is limited primarily to control of various oak species by aerial application of the herbicide. If silvex is canceled for this use, most users probably will choose not to treat large areas formerly treated with silvex because no comparably-effective alternatives are available. These users will save from $4.60 to $13.00 per acre in control costs. These savings, however, will be offset by lower revenues from reduced production. Those silvex users who need only spot treatments on smaller tracts will be able to obtain some degree of control with one or more of the alternatives now available, since aerial application would be unnecessary. The aggregate impact on users will be small because few acres are treated with silvex now.

The economic impact of cancelling silvex for range would be negligible at consumer and national levels because silvex is now used on so few acres of rangeland (approximately 0.2% of U.S. rangeland).

2. Rice

a. Pest Infestation and Damage

Weeds reduce the yield and quality of rice in the U.S. on approximately 2.5 million acres. Herbicides are used on about 98% of commercial U.S. rice acreage. Fields are frequently treated more than once per year. Most treatments are made by custom aerial applicators. It has been estimated that the total cost of weed control and direct losses from weeds is several hundred million dollars per year.

Conditions favorable for growing rice also favor the growth and reproduction of many terrestrial, aquatic, and semi-aquatic weeds. Rice weeds reduce yields by direct competition and reduce quality through contamination of the harvested grain with weed seeds. Weeds in rice produce an abundance of seed. Once these infest the land, they are difficult to remove and may remain viable in the soil for many years.

Silvex is used annually on only 2000 rice-growing acres in the United States. The principal weed pests for which silvex is used include hemp sesbania, northern jointvetch, morningglory, ducksalad and redstem. Without weed control, significant yield and quality reductions on rice in the silvex use area could occur.

b. Use of Silvex and Alternatives

(i) Current Use of Silvex and Alternatives

Silvex use on rice is confined to the lower Mississippi Valley region (Arkansas, Northern Louisiana, Mississippi and Missouri). Silvex is used annually on 2,000 acres out of approximately 2.5 million rice-growing acres in the U.S. that receive some herbicide treatment.

Various herbicides and cultural practices are commonly employed to control rice weeds. Current practices generally combine chemical and cultural controls. There is no information which suggests that cultural controls would provide adequate control of rice weeds in the absence of any chemical controls. Thus, it is likely that chemical alternatives to silvex would be used in conjunction with cultural controls if silvex were canceled for use on rice.

Herbicides most frequently used on rice include propanil and molinate, which together account for 73% of all herbicide acre-applications to rice. These two herbicides are used principally to control grass weeds; however, propanil controls certain broadleaf and aquatic weeds that are controlled by silvex. 2,4-D is the only other herbicide used in appreciable quantities in the four-state silvex use area. Other herbicides, MCPA, bifenox, bentazon and oxadiazon may also be used in place of silvex. They are currently used in other states.

c. Comparative Efficacy and Cost of Silvex and Alternatives of Use on Rice

Silvex controls most broadleaf, aquatic and sedge weeds. Silvex, however, injures soybeans, a crop commonly grown in rotation with rice. Silvex also damages cotton, a crop commonly grown in areas adjacent to rice-growing acreage. These phytotoxic properties of silvex explain why silvex in used on few acres; rice growers prefer to use 2,4,5-T, which is less phytotoxic.

Propanil is currently applied to about 95 percent of the southern rice-producing area for early season control of grasses. Propanil selectively kills barnyard grass and many other grasses, aquatic, broadleaf and sedge weeds. Propanil controls hemp sesbania as effectively as silvex; however, propanil is less effective than silvex for controlling northern jointvetch, ducksalad, and redstem. If propanil were substituted on acres treated with silvex, yield and quality losses could occur.

2,4-D is applied for control of many broadleaf, aquatic, and sedge weeds. Its use, however, is curtailed in the lower Mississippi Valley because it is highly injurious to cotton. Most rice-growing states regulate the aerial application of 2,4-D to reduce damage from spray drift to nearby cotton fields. Therefore, 2,4-D may not be a viable alternative on all of the acreage now treated with silvex. 2,4-D is applied applied at midseason and apparently provides control of many broadleaf weeds as effectively as silvex. 2,4-D does not control northern jointvetch as effectively as silvex and is ineffective on grass weeds.

Several other herbicides used for control of rice weeds include molinate, MCPA, bifenox, bentazon and oxadiazon. Molinate may not effectively control hemp sesbania, northern jointvetch, ducksalad, morningglory or redstem. MCPA is not used in the silvex use area since it is thought to be relatively ineffective on hemp sesbania, northern jointvetch and Indian jointvetch. Bifenox, bentazon and oxadiazon are three new herbicides which are currently used to a limited extent; they do not appear to be as effective as silvex on most broadleaf and aquatic weeds.

Effective weed control systems in rice combine preventive, cultural, mechanical and biological methods with chemical control methods. Cultural/mechanical weed control practices include planting weed-free seed, summer fallowing, crop rotation, land leveling, seedbed preparation, special seeding methods, proper management of water, cultivation and hand weeding (in sparse weed infestations or in small areas). Although some of these methods are effective alone on some rice weeds, they are usually combined with chemical herbicide treatments.

d. Economic Impact of Cancellation of Silvex Use on Rice

If Silvex is cancelled for use on rice, current silvex users probably would use alternative chemical controls. 2,4-D and propanil would be the most likely alternatives. Use of these alternatives would cost $7.40 per acre-treatment (for 2,4-D) or $12.90 per acre-treatment (for propanil), compared with $9.50 per acre-treatment for silvex. Use of pronanil may necessitate a second treatment, bringing the annual cost of control with this herbicide to $21.80 per acre. Other possible alternatives are somewhat more expensive than silvex or these alternatives.

The economic impact of cancelling silvex for control of rice weeds would be negligible at consumer, user and national levels. This is due to the very limited use of silvex (less than 0.1% of all treated acres) and the availability of effective alternatives.

3. Sugarcane

a. Pest Infestation and Damage; Use and Efficacy of Silvex and Alternatives for Sugarcane Use

Silvex is used in Louisiana and Florida on sugarcane to control a variety of weeds that are resistant to 2,4-D. If uncontrolled, pest weeds would compete with sugarcane for nutrients, water, space and sunlight and would reduce crop yield.

Silvex is used on about 15% of all sugarcane harvested acres. Use of silvex has decreased in recent years; in 1976, approximately 33% of acres used for growing sugarcane were treated with silvex. The primary alternatives to silvex are a combination of dicamba and 2,4-D and 2,4-D alone.

Neither the combination of dicamba and 2,4-D nor 2,4-D alone is as effective as silvex. Therefore, some production losses, in some instances significant, may be expected from replacement of silvex by either of these alternatives.

b. Economic Impact of Cancellation of Silvex for Sugarcane Use

User level production value losses, in a worst-case situation, could amount to $4.0 million in Florida and $6.3 million in Louisiana if silvex were canceled and the combination of dicamba and 2,4-D or 2,4-D alone substituted for it. The maximum estimated yield losses would amount to only about 2% of total U.S. sugarcane production. Total U.S. sugarcane production accounts for only 18% of the U.S. sugar supply. Therefore, the cancellation of silvex would not result in measurable sugar price changes at the market or consumer level.

4. Orchard

a. Use of Silvex and Alternatives on Orchards

Silvex is registered for use in preventing apples and prunes from dropping from trees prior to harvest and for increasing fruit set on pears. Premature drops cause a complete economic loss of prune crops and a substantial loss in apple crops. Apples that have dropped prematurely may be sold for low-return uses such as cider. Prunes that have dropped early cannot be put to any commercial use.

In addition to minimizing preharvest apple drop and thus increasing aggregate production, silvex also acts to increase the quality of treated fruit by enhancing the coloring of red varieties. Use of silvex adds two to three weeks to apple trees' retention of fruit for on-tree ripening. The extra one to two weeks of on-tree ripening of fruit improves the color, sugar content and flavor of the sprayed fruit. These factors are particularly important for fresh-market growers who strive to maximize the percentage of their crops which grade out in the fresh-quality categories. The grade impacts of silvex are important to users in all areas, including the southernmost apple states (Georgia, North Carolina, South Carolina, Virginia), where growers attempt to produce high-color fresh quality apples for the highly-profitable early-season market.

Little quantitative data are available indicating the specific location or extent of silvex use on apples, prunes, or pears. A proprietary pesticide usage survey indicates that silvex use on apples in 1976 was limited to a few thousand acres as was silvex use on prunes. This survey data contrasts with information provided by horticultural personnel, who believed that use was substantially higher than that indicated by the survey data. Apparently, little silvex is applied to pears.

Currently, two alternatives to silvex are available for use on apples to control preharvest drop. NAA (1-Napthaleneacetic acid) is registered for apples both as an early season thinning agent and as a late season drop control agent. Alar (succinic acid 2,2-dimethyl hydrazide) is registered for premature apple drop control as well as for other growth regulating functions.

Neither NAA nor Alar is considered to be as effective as silvex for premature drop control. NAA is less effective than silvex in the southern apple states and is best suited for varieties other than Red Delicious, the apple cultivar on which silvex is principally used. Use of NAA also may require a second annual application in some cases, whereas silvex is applied only once a year.

Alar is a major alternative to silvex on apples since it is suitable for use on Red Delicious. Alar seems to be less effective than silvex for preharvest drop control and also may reduce fruit size. Alar will also adversely affect fruit shape the following year if applied within 60 days of harvest.

There are currently no registered alternatives to silvex for premature drop control on prunes. However, 2,4-DP, which is currently registered for some non-crop applications, has reportedly provided good prune drop control in field tests, and may be registered for this use in the future. There are no registered alternatives for silvex use on pears.

(b) Economic Impact of Cancellation of Silvex for Orchard Use

Substitution of Alar and NAA for silvex could increase apple production costs by as much as $1 million per year. Prune growers could incur revenue reductions of approximately $1.8 million per year if silvex were cancelled, assuming no suitable alternative becomes available.

If the increased apple production costs are absorbed by the growers, no impact will be felt by consumers. Even if the costs are passed on to the consumer, the retail price effect on apples would be negligible. Although some adverse impact on consumer prices would occur as a result of a cancellation of silvex for use on prunes, it is not possible to assess the magnitude of such an increase. Cancellation of silvex use on pears is unlikely to have any effect on consumer supply or the quality or price of pears because little silvex is applied for this use.

5. Non-crop Areas[7]

a. Use of Silvex and Alternatives on Non-crop Areas

Silvex is registered for control of many broadleaved and herbaceous weeds[8] in a variety of urban and rural non-crop areas. Silvex is used because of its relatively low cost, the broad spectrum of weeds it controls and its selectivity for control of undesirable plant species. Generally, the weed control achieved on these sites does not confer significant economic benefits.

Recent data on the usage of silvex for non-crop areas is not available. However, a 1974 publication reported that 60,000 lbs. a.e., of silvex were used for general maintenance on 30,000 acres of grounds at industrial, commercial and institutional sites. This area is a small proportion (1.7%) of the 1.8 million acres treated with herbicides for grounds maintenance.

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[7] "Non-crop areas" include: fencerows, hedgerows, fences (not otherwise included in suspended uses, e.g., rights-of-way, pasture); industrial sites or buildings (not otherwise included in suspended uses, e.g., rights-of-way, commercial/ornamental turf); storage areas, waste areas, vacant lots, parking areas.

[8] The weeds are numerous; they include the following broadleaved plants--pigweed, ragweed, lambsquarters, horsenettle, cocklebur, morningglory--and woody plants--poplar, cottonwood, wild cherry, maple, blackberry, honeysuckle, poison ivy, and wild grape.

Numerous chemical and non-chemical controls are available as alternatives to silvex. Chemical alternatives include herbicides, such as 2,4-D, picloram, dicamba, AMS, or amitrole. The most comparable alternatives are combination products, such as 2,4-D and picloram or 2,4-D and dicamba. Soil sterilants, such as sodium borate or sodium chlorate, control weeds that silvex controls but are effective primarily as preventive controls. Subsequent infestations sometimes may require follow-up treatments with conventional herbicides.

Mechanical methods of control, such as mowing or shearing, or manual methods could also serves as alternatives to silvex.

The efficacy of the alternatives compared with that of silvex is not known. The spectrum of weeds controlled will differ from that of silvex for the individual active ingredients. However, silvex's weed spectrum may be approximately fairly closely by using a combination product or by using multiple applications of different herbicides. It can be assumed that products listing weed species controlled by silvex on their labels are as effective as silvex at controlling those weeds.

Generally, no more than one treatment with silvex is needed annually to achieve control of the problem weeds. In some circumstances, one treatment will give comparable length of control of silvex, but other herbicides, such as 2,4-D alone or amitrole, may require more than one treatment annually. The length of control with mechanical or manual means is unknown.

b. Economic Impact of Cancellation of Silvex for Non-crop Uses

In general, effective alternatives to silvex exist for non-crop sites. Effective alternative combination products which provide equally long-term control at a comparable price are registered and available. Impacts on users of silvex will be felt in the form of increased control costs for the combination alternatives.

Little if any impact is expected at market and consumer levels because effective alternatives are available and because the economic value of weed control on non-crop sites is very small.

C. Determinations on Apparent Unreasonable Adverse Effects

For the reasons set forth in detail in the Position Document, the Agency has made the following determinations relating to the apparent unreasonable adverse effects on the non-suspended uses of silvex:

1. Determinations on Rangeland Use

The Agency has determined that the use of silvex on rangeland appears to pose risks which are greater than the social, economic, and environmental benefits of the use. The Agency has further determined that the available data on the exposure potential and benefits of use on rangeland are to some extent uncertain and/or incomplete, and that the necessary information may be developed through a public hearing for the review of these questions. Accordingly, the Agency has determined that the use of silvex on rangeland appears generally to cause unreasonable adverse effects on the environment when used in accordance with widespread commonly recognized practice.

2. Determinations on Rice Use

The Agency has determined that the use of silvex on rice appears to pose risks which are greater than the social, economic and environmental benefits of the use. The Agency has further determined that the available data on the exposure potential and benefits of the rice use are to some extent uncertain and/or incomplete, and that the necessary information may be developed through a public hearing for the review of these questions. Accordingly, the Agency has determined that the use of silvex on rice appears generally to cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice.

3. Determinations on Sugarcane Use

The Agency has determined that the use of silvex on sugarcane appears to pose risks which are greater than the social, economic, and environmental benefits of the use. The Agency has further determined that the available data on the exposure potential and benefits of use on sugarcane are to some extent uncertain and/or incomplete, and that the necessary information may be developed through a public hearing for the review of these questions. Accordingly, the Agency has determined that the use of silvex on sugarcane appears generally to cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice.

4. Determinations on Orchard Use

The Agency has determined that the use of silvex on orchards appears to pose risks which are greater than the social, economic and environmental benefits of the use. The Agency has further determined that the available data on the exposure potential and benefits of the orchard use are to some extent uncertain and/or incomplete, and that the necessary information may be developed through a public hearing for the review of these questions. Accordingly, the Agency has determined that the use of silvex on orchards appears generally to cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice.

5. Determinations on Non-Crop Uses

The Agency has determined that the use of silvex on fences, lumber yards, refineries, non-food crop areas, storage areas, wastelands, vacant lots, tank farms, industrial sites and other non-crop areas, not subject to the emergency suspension orders (i.e., the suspension orders applied to forests, rights-of-way, pastures, home and garden, aquatic weed control/ditch bank and commercial/ornamental turf) appears to pose risks which are greater than the social, economic and environmental benefits of the use. The Agency has further determined that the available data on the exposure potential and benefits of the non-crop uses are to some extent uncertain and/or incomplete, and that the necessary information may be developed through a public hearing for the review of these questions. Accordingly, the Agency has determined that the non-crop uses of silvex appear generally to cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice.

D. Initiation of Regulatory Actions

Based on the determinations summarized above and developed in detail in the Position Document, the Agency is initiating the following regulatory actions and this document shall constitute its notice of intent to initiate these actions:

(1) issuance of a notice of intent to hold a hearing pursuant to FIFRA §6(b)(2) to determine whether or not to cancel the use of silvex on rangeland;

(2) issuance of a notice of intent to hold a hearing pursuant to FIFRA §6(b)(2) to determine whether or not to cancel the use on rice;

(3) issuance of a notice of intent to hold a hearing pursuant to FIFRA §6(b)(2) to determine whether or not to cancel the use of silvex on sugarcane;

(4) issuance of a notice of intent to hold a hearing pursuant to FIFRA §6(b)(2) to determine whether or not to cancel the orchard uses of silvex;

(5) issuance of a notice of intent to hold a hearing pursuant to FIFRA §6(b)(2) to determine whether or not to cancel the non-crop use of silvex.

E. Statement of Issues

In accordance with §164.23 of the Agency's Rules of Practice (40 CFR 164), this part of the notice states the questions on which evidence relative to the non-suspended uses of silvex shall be taken at the §6(b)(2) hearing.

With respect to the use of silvex on rice, rangeland, sugarcane, orchards, and non-crop areas, evidence will be taken as to the following questions:[9]

(1) Whether the use of silvex on rangeland generally causes unreasonable adverse

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[9] Because the Agency plans to propose that this FIFRA 6(b)(2) hearing on the non-suspended uses of silvex be consolidated with a proposed FIFRA 6(b)(2) hearing on the non-suspended uses 2,4,5-T and the FIFRA 6(b)(1) hearing, already in progress, for the suspended uses of 2,4,5-T and silvex, the consolidated hearing would review uses of both silvex and 2,4,5-T. The statement of issues refers only to those issues which are specific to the non-suspended uses of silvex. It is important to emphasize that this Notice is specific to the non-suspended uses, and that other issues would be addressed in the hearing as a whole.

effects on the environment when used in accordance with widespread and commonly recognized practice;

(2) Whether the use of silvex on rice generally causes unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice;

(3) Whether the use of silvex on sugarcane generally causes unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice;

(4) Whether the use of silvex on orchards generally causes unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice; and

(5) Whether the use of silvex on non-crop areas generally causes unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice.

(6) Whether the use of silvex on rangeland,

rice, sugarcane, orchards, and non-crop areas will generally cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice unless modifications more restrictive than those currently employed are accomplished; and

(7) Whether, if modifications to the terms and conditions of registration are accomplished, the labeling of silvex products for these uses will comply with the provisions of FIFRA.

In considering these issues and whether or not to participate in a hearing on these issues, it should be clearly understood that these and other uses of silvex may be cancelled as a result of evidence presented and actions taken in the Section 6(b)(2) hearing.

IV. Procedural Matters

This Notice of Determination notifies the United States Department of Agriculture, the Scientific Advisory Panel, pesticide registrants and users, and other interested parties of the Agency's preliminary determinations relating to the risks and benefits of the non-suspended uses of silvex, and provides these entities and individuals with opportunity to comment on these determinations.

As discussed in section II of this notice, the Agency's decision to initiate the regulatory actions described in section III must be referred for review by the Secretary of Agriculture and the Scientific Advisory Panel. In accordance with FIFRA, the EPA position document setting forth in detail the reasons and factual bases for the regulatory actions which the Agency proposes and this notice of determination are being transmitted immediately to the Secretary of Agriculture and to the Scientific Advisory Panel for comment.[10]

The Agency also is transmitting copies of these documents to silvex registrants, and is offering registrants and other interested parties an opportunity to comment on the bases for the Agency's action by making copies of the Position Document available upon request. Interested persons may receive copies of the documents by communicating their requests to Michael Dellarco, Project Manager, Special Pesticide Review Division (TS-791), EPA, Room 447, 401 M St. S.W., Washington, D.C. 20460. Registrants and other interested persons will be given the same period of time to submit comments --30 days--that FIFRA provides for comments from the Secretary of Agriculture and the Scientific Advisory Panel.

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[10] FIFRA Section 6(b) also provides that upon a finding by the Administrator that suspension of a pesticide registration is necessary under §6(c) of FIFRA to prevent an imminent hazard to human health, he may waive these external review requirements. In his Emergency Suspension Orders Regarding Registrations of Pesticide Products Containing Silvex, the Administrator made such findings (44 FR 15901, March 15, 1979). Accordingly, in the Notices of Intent to Cancel the Registrations or Change the Classifications of Pesticide Products Containing Silvex and the Statement of Reasons (44 FR 15919, March 15, 1979), the Administrator specifically invoked that authority and waived the external review requirements for the actions initiated by the Suspension Orders.

After completion of these review procedures, the Agency will consider the comments received and publish an analysis of them, together with any changes in the regulatory actions announced in this notice which it determines are appropriate.

The Agency's analysis of the comments received during the external review period may lead to withdrawal or modification of the section 6(b)(2) notice of intent to hold a hearing. Alternatively, if the Notice is not withdrawn, the Agency intends to petition the Administrative Law Judge to consolidate the FIFRA section 6(b)(2) hearing on the suspended uses of silvex with the FIFRA section 6(b)(1) hearing on the suspended uses of silvex.

Until this external review phase is concluded and the Agency issues final notices, it is unnecessary for registrants or other interested persons to request a hearing to contest any regulatory actions resulting from issuance of this notice.

All comments on the proposed actions should be sent to the Federal Register Section, Program Support Division (TS-791), Office of Pesticide Programs, EPA, Room 447, East Tower, 401 M Street, S.W., Washington, D.C. 20460. In order to facilitate the work of the Agency and of others interested in inspecting the comments, registrants and other interested persons should submit three copies of their comments. The comments should bear the identifying notation OPP/30000/__, and should be submitted on or before ______________________.

Dated: 7/9/79

Steven D. Jellinek
Assistant Administrator
for Toxic Substances

SILVEX: POSITION DOCUMENT 1/2/3

U.S. ENVIRONMENTAL PROTECTION AGENCY
PROJECT MANAGER: MICHAEL DELLARCO

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Silvex: Position Document

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Silvex : Position Document

I. INTRODUCTION

During the past two years, the Environmental Protection Agency (EPA) has been gathering information about the closely related phenoxy herbicides, 2-(2,4,5-trichlorophenoxy) propionic acid (silvex) and 2,4,5-trichlorophenoxy acetic acid (2,4,5-T), as part of its Rebuttable Presumption Against Registration (RPAR) process in order to determine whether the registrations of these pesticides should be continued. This review was prompted in part by studies showing that silvex, 2,4,5-T, and/or TCDD (2,3,7,8-tetrachlordibenzo-p-dioxin), the dioxin contaminant of both 2,4,5-T and silvex caused reproductive and oncogenic effects in test animals.

On April 11, 1978, the Agency issued a notice of rebuttable presumption against all registrations of the herbicide 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) [43 FR 17116, 21 April 1978]. Subsequently, on February 28, 1979, responding in part to information developed through the 2,4,5-T RPAR, the Administrator ordered the emergency suspension of silvex for forestry, rights-of-way, pasture, aquatic weed control/ditchbanks, home and garden, and commercial/ornamental turf uses ("suspended uses") (44 FR 15897, 15 March 1979). At the same time, the Administrator also issued notices of intent to cancel these uses. These actions initiated public hearings on issues relating to the risks and benefits of these silvex uses.[*]

Because the data reviewed and analyzed for the suspension action indicated that the suspended uses of silvex created an imminent hazard for human health, the Agency accelerated its review of the use of silvex on rangeland, rice, sugarcane, orchards and non-crop[**] areas (non-suspended uses). These uses were assessed in terms of the RPAR risk criteria (40 CFR 162.11(a)), using data presented in the Emergency Decision and Order suspending certain uses of silvex (44 FR 15897, 15 March 1979), data and information on TCDD submitted in rebuttal to the 2,4,5-T RPAR, and other relevant information. From this review, the Agency has concluded that when used in accordance with widespread and commonly recognized practice, the non-suspended uses of silvex appear to cause unreasonable adverse effects on the environment. As a result, the Agency is issuing a notice of intent to hold a hearing to determine whether the non-suspended uses of silvex should be cancelled.

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[*] Suspension proceedings commenced on April 19, 1979, but were discontinued on May 15, 1979 after all registrants withdrew from the hearings. The first pre-hearing conference for the cancellation proceedings was held on June 5, 1979; the formal hearing will probably begin in the fall.

[**] The non-crop uses of silvex include use on fencerows, hedgerows, fences (not otherwise included in suspended uses, e.g., rights-of-way, pasture); industrial sites or buildings (not otherwise included in suspended uses, e.g., rights-of-way, commercial/ornamental turf); storage areas, waste areas, vacant lots, parking areas, and the other sites for which silvex use is registered.

This Position Document reviews the Agency's assessment of the risks and benefits of the non-suspended uses of silvex, particularly use on rice, rangeland, sugarcane, and orchards, and explains the bases for the Agency's decision to convene a hearing to determine whether to cancel these uses.

This Position Document contains four parts. Part I, this introduction, summarizes the legal provisions relating to the registration and cancellation of pesticides, and background information on the chemistry and uses of silvex. Part II is an evaluation of the data and information relating to the risks associated with the non-suspended uses of silvex. This part includes the Agency's analysis of laboratory data on silvex and TCDD, information on TCDD developed through the 2,4,5-T RPAR review, information on exposure potential of the uses of silvex, and other risk considerations. Part III reviews the benefits associated with the non-suspended uses of silvex on a use-by-use basis. Part IV discusses and explains the bases for the determination to hold a hearing on the risks and benefits of the orchard, sugarcane, rice, rangeland and the noncrop area uses of silvex.

A. Legal Authority

(1) Statutory Provisions

The Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA") [7 U.S.C. 136 et seq.] requires the Environmental Protection Agency (EPA) to regulate all pesticide products through review of the risks and benefits of the uses of these chemicals. A key provision is Section 12(a)(1)(A) of FIFRA which specifies that all pesticide products must be registered by the Administrator before they may be sold or distributed. Before a pesticide may be registered, however, the Administrator must determine that its use will not result in "unreasonable adverse effects on the environment," defined in Section 2(bb) of FIFRA as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." In other words, any decision on pesticide registration must take into account both risks and benefits from the pesticide's use.

Under Section 6(b) of FIFRA the Administrator may cancel the registration of a pesticide or change its terms and conditions of registration if it appears that the pesticide "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." For example, the Administrator may cancel the registration of a pesticide, or change its terms and conditions of registration, if its labeling does not comply with the misbranding provisions of FIFRA which require the labeling to contain the language "adequate to protect health and the environment" [FIFRA 2(q)]. The Administrator may also change the classification of any use of a pesticide if he determines that such a change "is necessary to prevent unreasonable adverse effects on the environment" [FIFRA 3(d)(2)].

Two types of proceedings are available under section 6(b) of FIFRA to cancel a pesticide registration, or modify the terms and conditions of a pesticide registration: FIFRA Section 6(b)(1) proceedings and FIFRA Section 6(b)(2) proceedings. In general, FIFRA section 6(b)(1) proceedings begin with a notice specifying the regulatory action which the Administrator is proposing. This action takes effect automatically, without hearings, at the expiration of a notice period prescribed by statute, unless the registrant or a person adversely affected by the notice requests a hearing within that period. If a hearing is requested, the regulatory action proposed by the Administrator does not take effect; however, at the conclusion of the hearing, the Administrator may implement the proposed action, if he determines that it is appropriate to do so based on the record developed in the hearing.

Section 6(b)(2) proceedings, on the other hand, begin with a general notice specifying the issues which the Administrator desires to have explored at a hearing. Unlike section 6(b)(1) proceedings, Section 6(b)(2) proceedings do not include an initial proposed regulatory solution which would take effect automatically if a hearing is not requested. Interested persons may participate in the hearing; at the conclusion of the hearing, the Administrator may take whatever action he deems appropriate, based upon the record developed in the hearing, including cancellation of a pesticide registration or modification of the terms and conditions of registration.

(2) The RPAR Process

The Rebuttable Presumption Against Registration (RPAR) process provides a mechanism through which the Agency gathers risk and benefit information about pesticides which appear to pose risks of adverse effects to human health or the environment which may be unreasonable. Through this process, the Agency invites pesticide registrants, environmentalists, and other interested persons to participate in the Agency's review of suspect pesticides and in reaching an open and balanced decision on the continued use of the pesticides.

The RPAR regulations at 40 CFR 162.11 (a)(5) prescribe regulatory criteria for the Agency's preliminary assessment of a pesticide's health and environmental effects and provide that an RPAR shall arise if the Agency determines that any of the risk criteria have been met. The Agency generally announces that an RPAR has arisen by publishing a Notice in the Federal Register. Once a rebuttable presumption has arisen, registrants, applicants, and interested persons may submit evidence in rebuttal or in support of the presumption. Information on the economic, social, and environmental benefits of any use of the pesticide may also be submitted.

If the presumptions of risk are not rebutted, the benefits evidence submitted and that gathered by the Agency must be evaluated and considered in light of the risk information. If the Agency determines that the risks appear to outweigh the benefits, the Agency can initiate action under FIFRA section 6(b)(1) to cancel the registration for a use or to modify the terms and conditions of registration for the use. FIFRA Section 6(b)(2) proceedings are appropriate (among other situations) where a pesticide use appears to pose unreasonable adverse effects, and additional information on risks or benefits would assist the Agency in making a decision on the ultimate fate of the pesticide use.

B. Background Information Relating to Silvex

(1) Chemical/Physical Characteristics

The herbicide commonly known as silvex, 2-(2,4,5-Trichlorophenoxy) Propionic Acid[*/], has an empirical formula of $C_9H_7CL_3O_3$ and a molecular weight of 269.53, with a melting point of 181.6°C. At 25°C, it is essentially insoluble in water (0.014%) but is relatively soluble in organic solvents such as acetone (15.2%), methanol (10.5%), ether (7.13%), and benzene (0.16%) (Raw, 1970). The esters of silvex are formulated to be emulsifiable in water and soluble in most oils, while its amine salts are soluble in water but insoluble in petroleum oils (Packer, 1975). A water soluble salt with triethanolamine, called silveramine, is also produced.

[*/] Also called 2-(2,4,5-trichlorophenoxy) propanoic acid, sylvex, 2,4,5-TP or fenoprop.

(2) Manufacturing Process and Contaminants

Silvex is produced commercially by hydrolysis of 1,2,4,5-tetrachlorobenzene using methanol and sodium hydroxide to yield the sodium salt of 2,4,5-trichlorophenol (2,4,5-TCP).[*] This product is reacted with 2-chloroproponic acid in hot aqueous sodium hydroxide to form the sodium salt of silvex, which is converted to silvex by the addition of acid. The acid form of silvex can be reacted readily with a variety of alcohols to produce a large selection of esters, and with amines to produce amine salts (Packer, 1975).

During the first step in the manufacturing process of silvex, if temperature and pressure are not carefully controlled, condensation reactions can occur to produce large quantities of highly toxic polychlorinated dibenzo-p-dioxin contaminants. The term dioxin does not apply to any one compound but to a group of related substances, which are distinguished by the number and orientation of chlorine atoms they contain. The particular dioxin formed is dependent on the chlorophenols present (Poland and Kende, 1976). Dioxin toxicity varies with the position and numbers of chlorines attached to the phenol rings.

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[*] 2,4,5-TCP is the subject of a separate Rebuttable Presumption Against Registration (RPAR) Position Document. It is discussed in this document because both it and its contaminant 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) may be present in some commercial silvex and in silvex samples used in animal experiments.

In the silvex manufacturing process an especially toxic dioxin, 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), is formed when the reaction temperature is excessive (Fike and Seaton, 1962), most commonly at temperatures above 160°C. Halogens at the 2, 3, and 7 positions are known to produce the most toxic dioxins (Burger, 1973). In the case of TCDD, the chlorine atoms are attached at the 2, 3, 7, and 8 positions which are considered the most toxic positions possible (Schwetz et al., 1973). The dioxin contaminant in silvex is of particular concern because of its extremely high toxicity, and because of the apparent inability of manufacturers to produce silvex without the contaminant, TCDD.[*/]

TCDD occurs as a white crystalline solid. It is 99.5% decomposed at 800°C. TCDD has the following solubility in various solvents at 25°C (Harvey, 1973):

Solvent	Solubility (wt. per cent)
Acetone	0.011
Benzene	0.057
Dimethylsulfoxide	<0.01
Methanol	0.001
Water	0.00000002 (0.2 ppb)

[*/] Current methods for manufacturing silvex produce TCDD as a by-product of the manufacturing process. Although silvex manufacturers attempt to remove this contaminant, TCDD cannot be completely removed. An EPA contract laboratory has measured the TCDD content in 8 recently produced commercial samples of technical grade silvex from two different manufacturers. The contractor reported that the TCDD content in these samples ranged from 0.012 to 0.024 ppm (limit of detection 0.01 ppm) Therefore, because TCDD is present as a low-level contaminant in commercial samples of silvex, references in this document to "silvex" or the "pesticide product" mean silvex that is contaminated with TCDD.

Since 1950, most of the chemical industry has known that large quantities of TCDD may be formed as a byproduct of the 2,4,5-TCP manufacturing process if the procedures are not carefully controlled. After concern arose in 1969 about the extremely toxic effects of TCDD, manufacturing methods were changed and carefully controlled by manufacturers. By 1971 industry had reduced TCDD content in commercial phenoxy herbicides to less than 1 ppm (Milnes, 1971; Grieg et al.,1973; Hussain et al., 1972). Current U.S. manufacturing specifications require silvex presently being sold to contain less than 0.1 ppm TCDD.[*/] (Dow Chemical Co., FIFRA Docket No. 295).

(3) Registered Uses and Production

Silvex is a selective herbicide for control of woody plants, broadleaf herbaceous weeds, and aquatic weeds. Registered uses include selective weed control in rice, sugarcane, pastures, rangeland, rights-of-way, forest site preparation, conifer release, industrial areas, fence rows, highways, commercial turf, home lawns, uncultivated agricultural land, waste land, aquatic sites (still water, lakes, and ponds) and ditch banks. At sub-herbicidal concentrations, silvex is used as a plant regulator to retard preharvest fruit drop on plums (prunes), pears, and apples.

Silvex is effective against a number of weed species resistant to 2,4-dichlorophenoxy acetic acid (2,4-D) and 2,4,5-T. Among the silvex target species are wild lettuce,

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[*/] See footnote, page 9.

chicory, nightshade tievine, alligatorweed, post oak, blackjack oak, sand shinnery oak, yucca, salt cedar, chickweeds, spurges, black medic, and poison ivy.

Silvex is commonly applied postemergence in water, oil, oil-water, and granular carriers using conventional aerial and ground equipment. The most commonly used formulations are the low volatile esters for brush, rice , sugarcane and mixtures with 2,4-D, or 3,6-dichloro-o-anisic acid (dicamba), for lawn and turf weed control (Thompson, 1975). Silvex also occurs in formulations mixed with triethanolamine (silveramine) or 2,4,5-T. Application rates vary from 0.75 to 4 pounds acid equivalent (a.e.)/acre, 6 to 16 pounds a.e./AHG and 6 to 8 pounds a.e./acre ft. depending upon target species and use site.

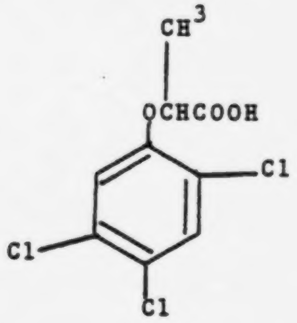
Silvex has been produced as a registered pesticide in the United States since 1953. According to EPA records, approximately 100 companies hold Federal registrations and formulate 247 registered products; 14 companies have former state registrations and formulate 25 products (Memo, 1979a).

(4) Environmental Fate

(a) Degredation

There is little data available regarding the persistence of silvex; however, several studies of the degredation of phenylalkanoic acids, a group that includes silvex, indicate that certain of these chemicals can be degraded photochemically or biologically (Crosby and Tutass, 1966; Gaunt and Evans, 1961). Alexander and MacRae (1964, 1965) have found degradation is limited when a halogen atom occurs at the meta position of an alkylated aromatic ring compound, or when the aromatic ring is linked to the alkyl ether side chain at the alpha position, independent of the halogen orientation. Both of these conditions exist in the silvex molecule. A likely degredation product of silvex would be 2,4,5-trichlorophenol. However, efforts to produce 2,4,5-trichlorophenol by treating saturated solutions of silvex with different concentrations of hydrochloric acid or sodium hydroxide at room temperature have not been successful (Bailey, et.al., 1970). Also, silvex was stable to irradiation in the dry state, and could be photolyzed to 2,4,5-TCP only when irradiated as the sodium salt in water (Crosby, 1969).

Fig. 1. Silvex molecule illustrating the alpha carbon atom on the alkyl chain and the meta position of the chlorine atom at position 5 of the aromatic ring:



(b) Persistence: Soils

Silvex has a relatively short half-life and appears to have an affinity for soil particles. Wiese and Davis (1964) estimated silvex movement through soil to range from 3 to 6 inches, using Pullman silty clay loam. Altom (1973) determined that the half-life of silvex in grassland soil was 14 days. Similar results were reported by Leng after application of silvex to grasses.

When considering the persistence of silvex, the persistence of its contaminant, TCDD, must also be considered. Helling et al. (1973) found that TCDD was not photodecomposed on soil. TCDD was found to be immobile in Norfolk and Lakeland sandy loams, Hagerstown silty clay loam, Barnes clay loam, and Celeryville muck, and was not leached further into soil by rainfall or irrigation. The investigators observed that TCDD's persistence was predictable since it is insoluble in water. During surface erosion of soil, however, lateral transport of TCDD could occur. The persistence of TCDD in Lakeland loamy sand and Hagerstown silty clay loam was also studied by Kearney et al. (1972). After one year these researchers recovered 56 and 63% of the originally applied TCDD in Hagerstown and Lakeland soils, respectively.

(c) Persistence: Water

Phenoxy chemicals entering water may be lost by volatilization, degradation, adsorption on sediment, adsorption by biota, and dilution as additional stream water passes through the site. Almost all authorities agree that there is adsorption on bottom sediment (Bailey et al.,1970; Frank and Comes, 1967).

In October 1965, the U.S. Geological Survey initiated a limited program of pesticide monitoring of 11 waterways in the western United States (Brown and Nishioka, 1967) where the probability of observing pesticide residues would be greatest. Pesticides chosen for analysis included the insecticides aldrin, DDD, DDE, DDT, dieldrin, endrin, heptachlor, heptachlor epoxide, and lindane, and the herbicides 2,4-D, 2,4,5-T, and silvex. The authors reported that no herbicide was found at any time at any station during the first year of the sampling program (limit of detection: 5ppt). Manigold and Schulze (1969), reporting on the results for October 1966 to September 1968, observed that beginning in August 1967, 2,4-D, silvex, and 2,4,5-T had been detected frequently. Silvex was found in 10 of the 235 samples at concentrations ranging from 0.01 to 0.21 ppb.

The National Interium Primary Drinking Water Regulations (EPA, 1977) allow up to 10 ppb of silvex in drinking water. However, these regulations are meant to apply in the event silvex is found in water. Deliberate addition of silvex to drinking water sources is not sanctioned by these standards.

Kearney et al. (1972) concluded that contamination of underground water supplies with TCDD seemed very unlikely, since vertical movement of TCDD did not occur in a wide range of soil types. The fact that no leaching occurred, however, would not preclude runoff contamination when soil erosion is significant (Helling et al., 1973).

(d) Transport

There are few published studies regarding the translocation of silvex and its TCDD contaminant in plants. Isensee and Jones (1971) measured uptake of TCDD from soil by two crop species. Oats (*Avena sativa*) and soybeans (*Glycine max*) were grown in Lakeland sandy loam soil treated with 0.06 ppm TCDD. The tops of these plants were harvested at intervals to maturity. Mature oats and soybean tops contained less than 1 part per billion (ppb) TCDD. TCDD was detected (detection limit: 1 ppb) in mature oat grain, while no TCDD was found in the bean of soybeans. The authors concluded that soil uptake of TCDD by plants was highly unlikely, since little or no TCDD was taken up by oats or soybeans under the conditions of this experiment.

(e) Fish and Wildlife

Generally, silvex esters are considered to be more toxic to fish and aquatic invertebrates than the silvex salts. The concentration of silvex that kills 50% of the number of fish exposed (LC_{50}) in 48 hour or 96 hour laboratory studies ranges from 0.14 to 70 ppm for silvex esters in contrast to 14 to 540 ppm for silvex salts (Swabey and Schenele, 1963; Hiltibran, 1967; Butler, 1965). Furthermore, the data indicate that the butoxyethanol ester (BEE) is the most toxic silvex formulation to fish (Reinert, 1975). Similarly, 48-hour and 96-hour LC_{50} estimates for aquatic invertebrates range from 0.2 to greater than 100 ppm depending on the silvex formulation used and the species tested (Burtler, 1965; Crosby and Tucker,1966; Sanders, 1970).

In contrast, benthic fauna were observed to increase in direct proportion to the amount of silvex applied to a Missouri pond (Harp and Campbell, 1964). The pond that was partitioned and treated with 0, 2.8, and 4.6 ppm of silvex potassium salt. The most abundant invertebrates sampled throughout the course of the 13-month study were oligochaete worms, odonates, leeches and snails. Only the Chrysops (grove flies) populations were reduced by the silvex treatment.

Comparative data regarding the toxic effects of silvex formulations in wild mammals or avians is limited To date, there have not been any field studies conducted on the toxic effects of silvex on wildlife; published reports have been limted to studies of laboratory and domestic animals. Available evidence from avian studies indicate that silvex esters are more toxic to young birds than silvex acid (Stickel, 1964; Tucker and Crabtree, 1970 and Heath et al., 1972).

Studies by Moffett and co-workers suggest that silvex is relatively non-toxic to honey bees. In separate experiments, silvex propylene glycol butyl ether ester (PGBEE) was tested for its effect on brood production, and mortality in both new born worker bees and adult bees. The authors concluded that silvex is not toxic to bees and that adverse effects to hives could be attributed to the use of silvex with diesel oil as the carrier(Moffett et al., 1972; Morton and Moffett, 1972; and Morton et al., 1972).

(f) Bioaccumulation

Suggestive evidence exists which indicates that silvex residues may persist in wildlife. In a study of water fowl collected where silvex had been applied at 20 lbs ai/acre seven months earlier, 36% (5 of 14) of birds sampled contained silvex residues ranging from 0.06 to 0.20 ppm. Similarly, in field trials of silvex as an aquatic herbicide by the U.S. Army Engineers, silvex residues of 0.053 ppm were found in fish 35 days after silvex treatment at 8 lbs. ai./acre.

Woolson et al. (1973) conducted a study to determine if TCDD residues could be detected in tissue extracts of the bald eagle (Haliaectas leucocephalus) as a representative of the top of a food chain. Nineteen bald eagle carcasses from fifteen states were examined between 1966 and 1971. No dioxin residues were detected at a level of 0.05 ppm TCDD, the lower limit of detection. The authors stated that the non-detection of dioxin residues could imply that there was no dioxin build-up in the food chain; that the build-up was less than the detectable level of their analytical equipment; that the eagles examined were not contaminated although other samples might be; or that other species could feed on a different food chain to accumulate dioxins.

Isensee and Jones (1975) exposed several organisms in a model aquatic ecosystem to ^{14}C-labeled TCDD for up to 31 days to determine the distribution and bioaccumulation potential in an aquatic environment. Soil with 0.0001 to 7.45 ppm adsorbed ^{14}C-TCDD was placed in aquaria containing snails (*Physa* sp.), a few strands of algae (*Oedogonium cardiacum*), and old aquarium water containing various diatoms, protozoa, and rotifers. Duckweed (*Lemna minor*) plants were also added to one aquarium. Samples of daphnids were taken for analysis at 30 days, and mosquito fish (*Gambusia affinis*) were added to each tank. Three days later all of the organisms were removed for analysis, and two fingerling channel catfish (*Ictalurus punctatus*) were added to each tank and exposed for six days.

The authors stated that all organisms in both treatment and control tanks prospered during this exposure period, indicating that TCDD was not toxic at the concentrations used. TCDD accumulated in all organisms. At the highest TCDD concentration (7.45 ppm) algae accumulated 6,690 ± 960 ppb TCDD; snails, 1,820 ± 170 ppb; daphnids, 10,400 ± 480 ppb; and Gambusia, 1,380 ± 220 ppb. Catfish were not analyzed for TCDD residues. At the second highest TCDD concentration (3.17 ppm), however, catfish accumulated 720 ± 130 ppb TCDD. The authors stated that accumulation in all of the test organisms from soil containing 0.1 ppb TCDD is important since this concentration approaches the concentration which would occur under normal field use of 2,4,5-T.

The authors concluded that the data suggested that under certain circumstances (e.g., discharge of storm runoff from recently treated rangeland into a small pond), water-eroded surface soil or debris may contain enough TCDD for measurable residues to accumulate in fish or other aquatic organisms. However, the authors speculated that TCDD, orginating from 2,4,5-T applications, discharged into large lakes, streams, or estuaries would probably become sufficiently diluted so that no measurable accumulation would occur.

In contrast to the results reported by Isensee and Jones, Norris and Miller (1974) reported that adverse effects were irreversible in guppies exposed to 0.1, 1.0, or 10.0 ppb of TCDD for 120 hours. All of the fish died by the 37th day after the exposure period.

(5) Residues in Man and Animals

Sauerhoff et al. (1976) studied the fate of silvex following oral administration to man. Volunteers ingested a single 1.0 mg/kg dose of analytical grade silvex with a purity greater than 99% and less than the detectable level (0.01 ppm) of TCDD. Blood, urine, and feces were collected at intervals for up to 186 hours after ingestion. Approximately 65% of the silvex ingested by these subjects was excreted in the urine within 24 hours. The plasma silvex concentration increased rapidly following ingestion and after 2 to 4 hours reached a peak of approximately 6.0 ug/g plasma. The plasma clearance was found to be biphasic with a half-life of 4.0±1.9 hr in the first phase and 16.5±7.3 hr in the second phase. Total recovery of silvex and its conjugates in urine and feces ranged from 66.6% to 95.1% of the administered dose with a mean value of 80.3%. No trichlcrophenol conjugates were found in the urine. Only small amounts of silvex and silvex conjugates were found in feces. The authors concluded that this may represent unabsorbed compound excreted in bile and eliminated from the body in feces.

The National Human Monitoring Program for Pesticides, through its cooperative arrangement with the Health and Nutritional Examination Survey II (Hanes II project), is currently analyzing human urine samples for silvex, 2,4,5-T, and 2,4,5-TCP (Memo,1977). The survey is scheduled for completion in 1979; however, preliminary results on 864 samples show measurable amounts of silvex in 3 samples, at levels as high as 33 ppm, and trace amounts in 10 samples.

Phenoxy acetic acids are relatively strong acids, and animals rapidly excrete them unchanged in their urine In their study of the fate of atrazine, kuron, silvex, and 2,4,5-T in the dairy cow, St. John et al. (1976) found that dairy cows given 2,4,5-T and silvex in their feed at 5 ppm for four days, completely eliminated both 2,4,5-T and silvex as soluble salts in the urine two days after dosing stopped. Sauerhoff et al. (1976) fed rats a single oral dose of 5 mg/kg ^{14}C silvex and recovered 77.54±5.05% of the radioactivity in urine and 16.5±7.74% of the radioactivity in feces However, confirmatory analysis that the radioactive material was silvex or silvex metabolite(s) was not conducted in the study.

Experimental results suggest that liver and kidney are the main sites for silvex clearence activity. Sauerhoff et al. (1977) treated rats with a single intravenous injection of 5 mg/kg or 50 mg/kg of silvex in an aqueous solution. They sacrificed the animals at 8 hours and 216 hours after injection and analyzed several tissues for silvex. The highest ^{14}C levels were recorded in the liver and the kidney at both doses. These findings were confirmed by separate experiments measuring the half-life of silvex clearance from plasma and bile which indicated that silvex is rapidly removed from the circulatory system to the liver and then rapidly excreted from the body in urine. Similar results were obtained in a preliminary report from a two-year chronic toxicity feeding study with TCDD by Dow Chemical USA (1977) (reported). Female rats ingesting 220 ppt TCDD/day or 2,200 ppt TCDD/day were noted to have high TCDD residues in liver and in fat at both treatment levels. The preliminary report gives no residue data for treated males, or for controls of either sex.

Zitko (1972) assayed chlorinated dibenzodioxin residues in aquatic animals, but was unable to detect these compounds (detection limit: 0.04 ppm for TCDD) in any of several aquatic animals from Canadian locations. The author had selected species from high trophic levels of the aquatic food web to measure cumulative pesticide contamination. More recently, using improved analytical methods for detection of dioxin at ppt levels, Baughman and Meselson (1973) found mean TCDD levels ranging from 18 ppt to 810 ppt in fish and crustaceans taken from Vietnamese rivers in August and September, 1970. TCDD levels tended to be higher in fish from interior rivers than in those from seacoast locations. In comparison, Baughman and Meselson (1973) found less than 3 ppt TCDD in fish obtained in a market in Cape Cod, Massachusetts. In another study, Matsumura and Benezet (1973) placed TCDD-coated sand directly in an aquarium containing brine shrimp, mosquito larvae, and fish (silverside). TCDD pickup was low in fish (2 ppb) and brine shrimp (157 ppb) under the experimental conditions. But mosquito larvae, which are bottom feeders, showed a surprisingly high rate of accumulation (4,150 ppb). The authors concluded that TCDD was not likely to accumulate in as many biological systems as DDT because of TCDD's low solubility in water and lipids, as well as its low partition coefficient in lipids.

(6) Residues in Food Products

Available data indicate that silvex residues may occur in foods. When sprayed on oranges, a silvex ester was hydrolyzed to the free acid, conjugated in the peel and persisted for several months (Hendrickson, 1969). Leidy et al. (1975) did not detect silvex in harvested apples 29 to 91 days after the application of silvex to the ground cover under apple trees. However, Cochrane et al. (1976) reported that direct application of a 20 ppm solution of silvex to apple trees (to prevent fruit drop) resulted in residues in unwashed fruit of 0.097 ppm initially, 0.046 ppm at harvest (day 10) and 0.036 ppm after 4 months in storage. Also after storage, washed fruit contained 0.015 ppm; washed and waxed fruit contained 0.014 ppm.

Studies where cattle and sheep were fed rations containing silvex for several weeks and then immediately slaughtered, indicate that silvex residues ranging from 0.6 to 18.0 ppm can be found in muscle, fat, liver, and kidney. However, when animals were allowed to withdraw from the treated feed, residue levels decreased markedly, often below 0.05ppm the limit of detection in these studies (Leng, 1972; Clark, 1975). Although Duggan et al. (1967) reported that silvex residues of 0.018 and 0.029 ppm were found in two composite samples of dairy product in 1965-1966, silvex residues have not been detected in total diet studies since that time (Martin and Duggan, 1968; Corneliussen, 1970, 1972; Manslee and Corneliussen, 1974).

C. Regulatory History

(1) Tolerances

A tolerance of 0.05 ppm has been established for silvex in or on pears (the raw agricultural commodity) resulting from post harvest application of the triethanolamine salt of silvex to pear trees. (40 CFR, 180.340). There are also interim tolerances of 0.1 ppm for silvex on sugarcane and pre-harvest application to apples and plums for prunes (40 CFR 180.319). No tolerances have been set specifically for TCDD in or on food crops. However, 40 CFR 180.302 establishes a tolerance of 0.05 ppm for hexachlorophene on cotton seed, with a stated limitation that the technical grade fungicide shall not contain more than 0.1 ppm TCDD. The limitation does not constitute a tolerance.

(2) Other

Regulatory Action

Silvex was developed and registered as a herbicide on brush shortly after World War II. Since then, it, along with 2,4,5-T, has been the subject of several Federal regulatory actions.

Initially, silvex was classified as a non residue, zero tolerance chemical. However, on April 13, 1966, the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA) published an announcement in the Federal Register abolishing the "No Residue and Zero Tolerance" concepts. Future registrations would be granted on the basis of either "Negligible Residue" or "Permissible Residue." Industry was given until December 31, 1967, to comply by obtaining tolerances for residues of silvex in all treated food, feed products, and byproducts. In addition none of the old registrations would be continued beyond December 31, 1970.

Following this action, a series of Pesticide Registration (PR) Notices were issued over several years, extending certain "no residue" and "zero tolerance" registrations beyond the December 31, 1967, deadline for obtaining residue tolerances. Among uses of silvex extended beyond the deadline were uses on pasture grasses and rangeland; on apples, pears, plums, rice, and sugarcane; and in lakes and ponds.

PR Notice 70-22, published by the USDA on September 28, 1970, addressed the presence of chlorodioxin contaminants in commerical poisons. This notice stated that the USDA had determined that certain toxic chlorodioxins (such as TCDD) may be present as contaminants in the basic materials used in formulating 2,4,5-T and silvex. The notice also stated that the presence of such chlorodioxins constituted a possible hazard to man since they had been found to be extremely toxic to laboratory animals, and that appropriate regulatory action would be taken under provisions of FIFRA since products containing chlorodioxins are considered to be in violation of FIFRA.

On July 20, 1973, a notice of intent to hold public hearings on all uses of 2,4,5-T was filed with the EPA Hearing Clerk under Section 6(b)(2) of FIFRA, as amended 1972. All federally approved uses of 2,4,5-T were to be explored in a public hearing scheduled for April 1974, following completion of an intensive monitoring program for detecting dioxin in the ppt range (38 FR 19869, July 29, 1973). On May 10, 1974, the FIFRA Section 6(b)(2) hearing was expanded to include all insecticides and herbicides having 2,4,5-TCP in their manufacturing process. These included silvex, erbon, and ronnel, as well as 2,4,5-T and 2,4,5-TCP, all of which may contain TCDD.

On June 24, 1974, EPA halted the FIFRA Section 6(b)(1) and 6(b)(2) proceedings initiated against 2,4,5-T and related compounds because of its inability to monitor food for TCDD residues with the necessary analytical precision. Although the hearing was terminated, the Agency stated that it "will continue its TCDD residue monitoring program and will take such further action as it deems appropriate once the results of the monitoring project are available" (39 FR 24050 June 28, 1974).

In 1976, 2,4,5-T, silvex and related chemicals*/ were placed on the original list of chemicals scheduled for pre-RPAR review, because of adverse effects that were observed in test animals exposed to 2,4,5-T. Much of the concern centered around TCDD, the extremely toxic contaminant found in these chemicals.

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*/ The related chemicals were ronnel, erbon, and 2,4,5-trichlorophenol.

On April 11, 1978, EPA issued an RPAR with respect to pesticide products containing 2,4,5-T. The RPAR review for some uses of 2,4,5-T was terminated on February 28, 1979, when the Administrator suspended the use of 2,4,5-T on forests, rights-of-way, and pastures because he found that these uses presented an imminent hazard to human health.

At the same time, the Admnistrator also suspended the forestry, rights-of-way, pasture, aquatic weed control/ditch bank, home and garden, and commercial/ornamental turf uses of silvex because he found that these uses presented an imminent hazard to human health. The Administrator's action regarding silvex was based on data and information about TCDD presented in the 2,4,5-T RPAR Position Document 1, new information developed through the RPAR process, and studies reporting adverse effects in test animals exposed to silvex. An expedited hearing on the suspension orders was convened on April 19, 1979; on May 15, 1979, the hearing was discontinued.

In addition, shortly after the suspension orders were issued, Dow and other affected parties filed suit on March 6, 1979 in the United States District Court, Eastern District of Michigan, Northern Division for judicial review of this decision, requesting an immediate stay of the emergency suspension orders. The court denied plaintiffs' request for an immediate stay of the suspension order, and a hearing for a preliminary injunction was held on April 5, 6, 7, and 9, 1979. On April 12, 1979, the Court denied plaintiffs request for an injunction against the Agency's suspension orders.

II. RISK ANALYSIS

There are two key components to the assessment of any chemical-related risk: (1) assessment of the toxicological properties of the chemical, and 2) assessment of exposure to the chemical. The risk assessment itself is a summation of the conclusions in each of these areas. For example, a highly toxic chemical may pose low risks if exposure is low; conversely a compound of low to moderate toxicity may pose high risks if exposure is high. In the present instance, TCDD, is an extremely toxic chemical, whereas silvex is significantly less toxic to test animals. However, because commercial samples of silvex contain TCDD, pesticide products containing silvex may have adverse effects on human health.

The RPAR process requires the Agency to assess the risk potential of a pesticide in terms of the risk criteria set out at 40 CFR 162.11(a). Specifically, 40 CFR 162.11(a)(3)(ii)(A) provides that a rebuttable presumption shall arise "if a pesticide's ingredient(s)...(i)nduces oncogenic effects in experimental mammalian species or in man as a result of oral, inhalation or dermal exposure..." Section 162.3(bb) defines the term oncogenic as "the property of a substance or a mixture of substances to produce or induce benign or malignant tumor formation in living animals."

40 CFR 162.11(a)(3)(ii)(B) provides that "a rebuttable presumption shall arise if a pesticide's ingredient(s)...(p)roduces any other chronic or delayed toxic effect in test animals at any dosage up to a level, as determined by the Administrator, which is substantially higher than that to which humans can reasonably be anticipated to be exposed, taking into account ample margins of safety." This section reflects concern that chronic exposure to chemicals may result,among other things, in injury to the reproductive system and/or the fetus and provides that a rebuttable presumption shall arise if chronic chemical exposure in test animals produces such results.

The following data and information on toxic effects and exposure indicate that silvex and/or TCDD exceed the oncogenic effects and other chronic or delayed toxic effects risk criteria for issuance of a rebuttable presumption against registration. This data also indicates that these chemicals may pose risks of adverse effects on human health.

A. Toxicity in Test Animals

Studies have demonstrated that TCDD and/or silvex contaminated with TCDD can produce fetotoxic, teratogenic, and carcinogenic effects in experimental animals which have been exposed to these chemicals.*/ The occurrence of these effects in test animals indicates that humans who are exposed to TCDD and/or silvex may experience comparable effects. The Agency has extracted key data from the numerous studies for presentation in this document.

(1) Adverse Reproductive Effects

TCDD and silvex with TCDD produce fetotoxic and teratogenic effects such as death and reduced fetal size; skeletal deformities such as cleft palate; injury to internal organs such as intestinal bleeding, intestinal lesions, and abnormal kidneys; and post-partum effects such as reduced survival. These effects appear in several different mammalian strains and species, occur in all of the litters in some dose groups, and occur in rats at doses as low as 0.001 ug/kg of TCDD and 50 mg/kg of silvex.

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*/ Other studies have attributed additional adverse effects to silvex and/or TCDD exposure. The Agency is currently analyzing these studies to assess the serious implications suggested by their results.

(a) Exposure of Test Animals to TCDD [*]

(i) Fetotoxic and Embryolethal Effects

Fetotoxic and embryolethal effects have been reported for at least three different mouse strains, two different rat strains, and one strain of subhuman primates exposed to daily dosages of TCDD during the period of major organogenesis in gestation. For example, in studies using generally low-dose regimens of TCDD, Neubert and Dillmann (1972) reported that resorption sites (resorbed or dead embryos) occurred in 54% (7/13) of the litters at 0.3 ug/kg and in 100% (3/3) of the litters at 9.0 ug/kg for NMRI mice, compared to 24-32% (23/95 and 21/65) of litters exhibiting resorptions in control animals which had not been exposed to TCDD (Table 1). Sparschu et al. (1971) reported resorption of 100% (110/110) of the fetuses in Sprague-Dawley rats exposed to 8 ug/kg of TCDD, compared to 20% resorption (63/309) of the fetuses from the control animals. Khera and Ruddick (1973) reported 100% (77/77) resorption of fetuses at 4 ug/kg and 36% (56/153) at exposures of 1 ug/kg in Wistar rats, compared to 7% (3/152) in the control animals.

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[*] Except as otherwise specified, all reproductive data were derived from studies in which pregnant rodents were orally exposed to TCDD and/or silvex with TCDD during the second one-third of gestation by daily gavage or in which primates were chronically exposed before mating and during gestation. The pregnant rodents were sacrificed shortly before the scheduled birth of the offspring, and the fetuses were examined for abnormalities. Pregnant primates delivered offspring at term.

Table 1. Embryotoxic and Teratogenic Effects of TCDD on NMRI Mice[a]

Dose[b] (ug/kg)	Litters Affected/Viable Litters			
	Resorptions		Cleft Palate	
	#	%	#	%
0	23/95	24	6/95	6
oil	21/65	32	4/65	6
0.3	7/13	54	0/13	0
3.0	16/24	67	7/24	29
4.5	5/12	42	6/12	50
9.0	3/3	100	3/3	100
9.0	3/6	50	5/6	83

[a] Data from Neubert and Dillmann.

[b] All doses administered on days 6 to 15, except second 9.0 ug/kg dose which was administered on days 9 to 13.

Similar effects have been reported at higher dosages of TCDD. Neubert and Dillmann (1972) reported that a single dose of 45 ug/kg to NMRI mice on day 6 produced resorptions in 100% (3/3) of the viable litters, compared to resorptions in 24% (23/95) of the control litters. Courtney (1977) reported an average of 87% mortality in 6 litters of CD-1 mice orally exposed to 200 ug/kg, compared to an average mortality of 6% in 15 vehicle control litters (Table 2). This investigator also reported an average of 76% mortality in 6 litters of CD-1 mice exposed subcutaneously to 200 ug/kg of TCDD, compared to 14% in the six litters of control animals. Some of these studies also describe statistically significant weight depression in the surviving embryos (e.g., Sparschu et al. 1971).

These and other studies also reported that TCDD had no measurable adverse effects at some dose levels in some strains. For example, Khera and Ruddick (1973) reported no fetotoxic effects at 0.125 ug/kg in Wistar rats, and Neubert and Dillmann (1972) reported no teratogenic effects at 0.3 ug/kg in NMRI mice. Courtney and Moore (1971) reported that TCDD had no effect on fetal weight or embryonic mortality at 0.5 ug/kg in CD rats, and Sparschu et al. (1971) reported no effect at 0.03 ug/kg in Sprague-Dawley rats. However, subsequent experiments in the same species have demonstrated adverse fetal effects at even lower dose levels.

Table 2. Fetotoxic and Teratogenic Effects of TCDD in CD-1 Mice[a]

Dose (ug/kg per day)	Route of Administration	% Average Fetal Mortality/Litter	Average # Abnormal Fetuses per Litter	Anomalies/Total Fetuses		
				Cleft Palate %	Kidney Anomalies %	Club Foot %
25	Oral	6	4.6	3	34	3
50	Oral	13	8.1	19	72	7
100	Oral	14	8.3	66	71	13
200	Oral	87	1.5	100	100	14
400	Oral	97	0.4	100	50	50
25	Subcutaneous	36	6.7	82	53	11
50	Subcutaneous	56	5.0	79	58	17
100	Subcutaenous	72	3.5	85	95	0
200	Subcutaenous	76	3.1	100	38	18
5% anisole corn oil (0.1 ml)	Oral	6	0.8	0	1	4
DMSO[b]	Subcutaneous	14	0.2	0	0	1

[a] Data from Courtney.

[b] DMSO = dimethylsulfoxide.

Dow Chemical Company has recently completed a study of the effects of TCDD on reproduction in Sprague-Dawley rats exposed to low dose levels of this chemical for three generations. Dow concluded that "impairment of reproduction was clearly evident among rats ingesting 0.01 or 0.1 ug/kg/day of TCDD. Significant decreases were observed in fertility, litter size, gestation survival, post-natal survival and postnatal body weight." In addition, exposure to 0.001 ug /kg/day of TCDD, the lowest level tested in this study, resulted in statistically significant increases in the percentage of pups dead at birth and/or dying before the end of three weeks of life and in the incidence of dilated renal pelvis in some generations.[*/]

[*/] Dow Chemical Company has claimed that the raw data and/or results of certain of its studies are "trade secret" or "confidential." An injunction issued on April 4, 1978, in the case of Dow Chemical Co. v. Costle, Civil Action No. 76-10087, U.S. District Court for the Eastern District of Michigan (Northern Division), arguably precludes EPA from disclosing this information at the present time. Although the relevant provisions of FIFRA have since been amended to allow disclosure of data such as this [see, e.g., FIFRA Sections 10(d) and 10(g)], the injunction has not yet been modified. EPA has requested the Court to modify the injunction, but until this has been done the Agency will not publicly disclose the data from the study. The summary presented in the text of this Position Document does not, in EPA's opinion, constitute disclosure of the allegedly "trade secret" data submitted by Dow and would not cause any harm to Dow's legitimate competitive interests. The data from the study may be made available to any party in a cancellation proceeding under an appropriate protective arrangement.

Recent reproductive studies in rhesus monkeys indicate that maternal exposure to TCDD results in an increased incidence of early spontaneous abortions and reproductive difficulties. The significance of these results in nonhuman primates should not be underestimated because of the close similarities between the reproductive systems of humans and monkeys. Long-term exposure to even minute quantities of TCDD resulted in a marked increase in spontaneous abortions in the first third of the gestational period, even where there was no evidence of maternal toxicity by clinical observation or biomedical testing. Monkeys exposed to 50 ppt TCDD (2.5 ng/kg per day) before and during pregnancy had a total fetal loss of 67% (50% by abortion and 17% as stillbirth) and fertility rate of 75%, compared with 0% and 100%, respectively, in the controls. Attempts to re-breed one of the aborters resulted in an additional early abortion (Schantz 1979; Spencer, 1979). When animals were treated with a higher dose, the fertility rate dropped to 25%, with one of the two gravid animals aborting in the first third of gestation. Irregularities in menstrual cycles, anovulation, and reduction in the reproductive hormones, progesterone and estrogen, were among the toxic effects seen at the higher dose. The investigators concluded that the reproductive abnormalities were most probably the result of hormone imbalance, and were apparently the result of the TCDD treatment, rather than general toxicity, because the hormonal alterations were observed before the animals became obviously ill (Allen et al., 1977; Barsotti 1979).

Early abortions have also been observed in monkeys where exposure has only been for a short period of the pregnancy. An accumulated dose of 1 ug/kg (1,000 ppt) of TCDD over a three-week period resulted in a 75% abortion rate, compared with 0% in the controls. All abortions in the treated animals were during the first third of the gestational period, and the only evidence of maternal toxicity was slight acnegenic response in one animal, observed months later. The viable offspring produced at this dose had abnormal palate development, and three of the four at a lower dose had debatable abnormal development in the same orofacial region (McNulty, 1979).

Although the experimental protocols and animal strains differ for the several studies cited, in each case TCDD significantly increased the incidence of resorbed embryos or stillborn animals relative to the rate observed in control animals not exposed to TCDD. The regular occurrence of embryonic death in studies by different investigators in primates and in different rodent strains indicates that exposure to TCDD during mammalian gestation may result in the death of the embryos and related maternal reproductive failure.

(ii) Skeletal Anomalies

Skeletal defects appear in six studies involving four different mouse strains. Courtney and Moore (1971) report the following incidences of cleft palate in the indicated strains exposed to 3 ug/kg TCDD: 71% (5/7) of litters of C57BL/6 mice, compared to none (0/23) in the controls; 22% (2/9) in litters of DBA/2 mice compared to none (0/23) in the controls; and 30% (3/10) for CD-1 mice, compared to none (0/9) in the controls (Table 3). Neubert and Dillmann (1972), also using 3 ug/kg of TCDD, reported 29% (7/24) of the viable litters had fetuses with cleft palate for NMRI mice compared to 6% (10/160) of the control litters (Table 1). Smith et al. (1976) reported cleft palate in 71% (10/14) of CF-1 mouse litters at 3 ug/kg, compared to none (0/34) in the controls (Table 4).

In exposures of shorter duration, Moore et al. (1973) reported cleft palate in 86% (12/14) of C57BL/6 mouse litters exposed on days 10-13 to 3 ug/kg, compared to none (0/27) in the control litters. Neubert and Dillmann (1972) reported cleft palate in 71% (10/14) of litters of NMRI mice exposed to a single 45 ug/kg dose on day 11, compared to 6% (6/95) of litters in the controls.

Courtney and Moore (1971) reported no cleft palate in any of the litters in CD rats exposed to 0.5 ug/kg. Similarly, Khera and Ruddick (1973), using Wistar rats, reported that the occurrence of the skeletal anomalies in the fetuses exposed to 2.0 ug/kg was comparable to the rate for the untreated animals.

(iii) Injury to Internal Organs

Exposure to TCDD produced injury to the kidneys and intestinal tracts of at least five different mouse and rat strains. Smith et. al. (1976) reported 28% (4/14) of litters with kidney anomalies at 3 ug/kg in CF-1 mice, compared to none (0/34) in the controls (Table 4). Moore et al. (1973) reported 100% (14/14) of litters with kidney anomalies in C57BL/6 mice exposed to 3 ug/kg on days 10-13, compared to none (0/27) in the control litters. Courtney and Moore (1971) reported kidney anomalies in 100% (10/10) of the litters of CD-1 mice at 3 ug/kg, compared to 33% (3/9) in the controls, and 67% (4/6) litters with abnormal kidneys in the CD rat at 0.5 ug/kg as compared to none (0/9) in the control litters (Table 3). Sparschu et al. (1971) reported hemorrhages or lesions in the intestine of 36% (36/99) of the examined fetuses of Sprague-Dawley rats exposed to 0.5 ug/kg, compared to none (0/246) in the control fetuses.

Table 3. Teratogenic Effects of TCDD in Mice and Rats[a]

Strain	Dose (ug/kg)	Litters Affected/Live Litters Cleft Palate #	 %	 Kidney Anomalies #	 %
Mouse					
CD-1	0(DMSO)	0/9	0	3/9	33
	1	1/9	11	5/9	56
	3	3/10	30	10/10	100
DBA/2	0(DMSO)	0/23	0	3/23	13
	3	2/9	22	8/9	89
C57BL/6	0(DMSO)	0/23	0	2/23	9
	3	5/7	71	7/7	100
Rat					
CD	0(DMSO)	0/9	0	0/9	0
	0.5	0/6	0	4/6	67

[a] Data from Courtney and Moore.

Table 4. Fetotoxic and Teratogenic Effects of TCDD in CF-1 Mice[a]

Dose (ug/kg)	Incidence of Cleft Palate in Litters per Live Litters #	 %	Litters With Resorbed Fetuses per Live Litters #	 %	Litters With Dilated Renal Pelvis per Live Litters #	 %
0	0/34	0	25/34	74	0/34	0
0.001	2/41	5	30/41	73	0/41	0
0.01	0/19	0	17/19	89	0/19	0
0.1	1/17	6	16/17	94	0/17	0
1.0	4/19	21[b]	18/19	95	1/19	5
3.0	10/14	71[b]	11/14	78	4/14	28[b]

[a] Data from Smith et al.

[b] Statistically different from controls by the Fishers exact probability test ($p < 0.05$).

(b) Exposure of Test Animals to Silvex

Silvex has been shown to produce fetotoxic effects such as fetal mortality, reduced body weight, skeletal anomalies, and injury to internal organs. The effects have been observed in test rodent species at maternal doses as low as 50 mg/kg (TCDD < 0.05 ppm). These results clearly indicate that silvex is fetotoxic and teratogenic in mammals.

Courtney (1977) reported significant incidences of increased fetal mortality and reduced fetal weight in CD-1 mice which had received prenatal exposure to silvex. Maternal subcutaneous exposure to 405 mg/kg silvex (TCDD < 0.1 ppm) resulted in 25% (33/132) fetal mortality and an average fetal weight of 0.87 g, compared with control values of 12% (19/171) and 1.03 g, respectively. Oral exposure to the same dose resulted in an average fetal weight of 0.83 g, compared with 1.01 g in the controls. An increased incidence of cleft palate was also observed among the treated fetuses. Oral exposure resulted in an incidence of 7% (7/95); subcutaneous exposure resulted in 3% (3/99). No cleft palates (0/260) were observed among the control animals.

Dow Chemical Company[*/] studied the reproductive effects of silvex and the propylene glycol butyl ether ester of silvex (silvex-PGBE), each containing less than 0.05 ppm TCDD. Sprague-Dawley rats were exposed to 25 to 100 mg/kg of silvex on days 6 through 15 of gestation. Significant effects on fetal mortality and birth weight were observed in the litters of treated dams. Skeletal anomalies, such as cleft palate, retarded ossification, and extra cervical ribs were observed among the exposed fetuses. Micropthalmia (abnormal smallness of the eyeball) and cardiovascular abnormalities were also seen. Similar effects were observed when animals were dosed with silvex-PGBE, or when dosed for three-day intervals during the period of early organogenesis.

In each of the studies cited above, some maternal toxic effects were observed. Courtney found some increased maternal weight gains and increases in liver to body weight ratios among the treated groups; Dow noted baldness (alopecia), lack of appetite and vaginal bleeding. However, the existence of maternal toxic effects does not negate the impact of the observed injury to and death of the fetus.

In summary, TCDD produces fetotoxic effects in test animals at the lowest doses tested. For example, maternal doses as low as 0.001 ug/kg in rats and 50 ppt in monkeys have increased lethality to fetuses. To date, a no-observed effect level has not been established for TCDD-related

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[*/] Dow Chemical Co. has also requested confidentiality for the results of this study. The discussion in the footnote in Section II.A.(1)(a)(i) of this document applies to these data.

effects on reproduction in any species tested. Exposure to silvex containing less than 0.05 ppm TCDD resulted in increased fetotoxicity at 400 mg/kg in mice and at 50 mg/kg in rats. No significant effects were observed below these levels.

(c) Risk of Adverse Reproductive Effects

Generally, a no-effect level is viewed as a toxicological endpoint, marking a level of exposure in animals which is "safe" because there are no observable adverse effects. Toxicologists generally assume that the animal no-effect level can serve as a base for estimating exposure levels which would be "safe" for humans. The "safe" level for humans is set at some level lower than the animal no-effect level to provide a "margin of safety" that takes into account differences in sensitivities between animals and humans, and differences in sensitivities among humans. This "margin of safety" does not represent an infallible indicator of potential hazard to humans. Error could be introduced because humans are more sensitive than the test species by a greater factor than normally allowed, or by the incorrect choice of a no-effect level.

The lowest level at which TCDD has no observable effects in test animals is crucial to the Agency's determination of the risk potential of silvex. TCDD is present in this pesticide as a low-level contaminant and thus will be present in the environment at low levels whenever and wherever silvex is used. If there truly were a no-effect level in animals, it would be reasonable to at least begin to estimate a possible "safe" level for humans and to assess the possible risk to humans by relating this assumed "safe" level to the level of the pesticide that may be in the environment, if that level were known. However, if there were no no-effect level, any use of silvex would result in potentially significant exposure to TCDD, because there would be no minimum level upon which to estimate a margin of safety. It is the Agency's position that no no-effect level has been found for fetotoxic effects resulting from TCDD exposure. Therefore, any exposure to TCDD or silvex containing TCDD must be considered potentially dangerous to the human fetus.

(2) Oncogenic Effects in Test Animals

Chronic exposure studies have shown that TCDD induces oncogenic responses in mice and rats at exceedingly low dose levels. These effects, together with data showing that TCDD is mutagenic, constitute substantial evidence that TCDD is likely to be a human carcinogen.

(a) Effects of TCDD

The Agency's Carcinogen Assessment Group (CAG) has concluded there is a sufficient evidence from animal studies to indicate that TCDD is likely to be a human carcinogen (Memo, 1979). Carcinogenic responses have been observed at doses as low as 210 ppt in rats.

Dow Chemical Company, a silvex registrant, studied the effects of TCDD on male and female Sprague-Dawley rats exposed to 22, 210 or 2200 ppt TCDD and reported that there were statistically significant increases in the incidence of hepatocellular carcinoma in female rats exposed to 2200 ppt TCDD (Dow Chemical U.S.A., 1977). After analyzing the raw data from this study, the CAG has concluded that the combined increase in the incidence of hepatocellular hyperplastic nodules and hepatocellular carcinoma in rats exposed to both the 2,200 ppt and 210 ppt levels is significant.[*] In another study using Sprague-Dawley rats, Van Miller et al. (1977) reported that 1000 ppt and 5000 ppt TCDD produced a carcinogenic response in male Sprague-Dawley rats. These observations tend to confirm the registrant's observations that TCDD produces an oncogenic response in the livers of male Sprague-Dawley rats.[**]

Further, a preliminary report of a not-yet-completed National Cancer Institute study tends to confirm these observations of a carcinogenic response in rats. A contractor for the National Cancer Institute has reported that TCDD is carcinogenic in the rats and mice used in that study.

CAG also emphasized that, at low levels, TCDD is a potent inducer of arylhydrocarbon hydroxylase, an enzyme system that contains an enzyme that is known to mediate the formation of epoxides, compounds which are potentially active carcinogenic metabolites. In addition, CAG reported that TCDD is mutagenic in the Ames test without the metabolic activation system. Its mutagenic activity is exhibited by frameshift mutations caused by intercalation between base-pairs of DNA (EPA, 1979).

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[*] Dow Chemical Company has also requested confidentiality for raw data supporting this finding. The discussion in the footnote in Section IIA (1) (a) of this document applies to these data.

[**] The CAG and an EPA audit found that this study had major shortcomings in design and conduct that limited the reliability of the data developed at dose levels lower than 1000 ppt.

Finally, CAG and others have compared the carcinogenic potency of TCDD with other known carcinogens (EPA, 1979) Based on these calculations, TCDD appears to be the most potent chemical carcinogen known (several times more potent than aflatoxin).

(b) Effects of Silvex

There is little definitive information regarding the oncogenic potential of silvex. Innes et al. (1969) reported no significant differences in the incidence of tumors between control animals and mice fed a diet containing 121 ppm silvex for 18 months. Similar results were obtained by Mullison (1966) who fed Kurosol, S.L., containing 53.3% silvex acid to rats at 10, 30, 100, and 300 ppm for two years. However, when beagle dogs were fed 190 ppm silvex potassium salt for two years and 560 ppm for one year, necrosis and fibroplastic proliferation in the liver were reported (Mullison, 1966).

(c) Risk of Oncogenic Effects

The Agency has examined the data showing that TCDD is carcinogenic at very low exposure levels in light of other information indicating that the use and distribution of silvex to the environment creates opportunities for human exposure to these chemicals. In view of the non-threshold concept upon which Agency Cancer Policy is based (Albert et al., 1977), any exposure to TCDD poses a significant risk of oncogenic effects occuring in the exposed population.

(3) Conclusion

In summary, available information supports the conclusion that there is a very real potential for human risks due to exposure to silvex and/or TCDD. These risks primarily relate to the oncogenic and fetotoxic effects of TCDD. Because TCDD is invariably present as a contaminant of commercial silvex, any exposure to silvex represents a significant potential risk to the exposed human population.

B. Exposure Resulting from the Use of Silvex

The use of silvex results in the distribution of the pesticide to air, water, non-target vegetation, soil, and other environmental components in areas where people live and work. As a result, people and their food and water supplies may be exposed directly or indirectly to silvex and its dioxin contaminant, TCDD. This section of the Position Document details information on the exposure potential resulting from the non-suspended uses of silvex, particularly use on orchards, sugarcane, rice, and rangeland. In some cases, information on exposure potential from these uses is derived from data on use practices, and in other cases this information is based on chemical residue data.

(1) Exposure due to Silvex Use on Rice

About 2,000 acres (1%) of the annual rice crop are treated with silvex to control broadleaf and aquatic weeds. The major use areas are in Mississippi, Arkansas, Louisiana, and Missouri.

Greater than 99% of all application of silvex for rice production is by fixed-wing aircraft which fly at speeds of 85 to 120 mph, 3 to 10 feet above the rice crop, when winds do not exceed 5 mph.

(a) Direct Exposure from Aerial Drift

The total rural population of the Delta region rice-growing counties is about 653,000 with an estimated 222,000 people residing within 1/2 mile of rice fields.

The average rural population density is 40 people/square mile. When the use of the pesticide results in drift to these areas of human work and habitation, people who live and work in the path of the drift may be directly exposed to the pesticide by inhalation and/or by dermal exposure to pesticide droplets in the airborn drift.

Cotton farmers who live in the Delta rice-growing region have reported drift onto their cropland and related crop damage (30,000/26:#302, #1888). These reports indicate that the pesticide has drifted beyond the spray area of the rice fields and into non-target areas. Such reports are consistent with studies showing that aerial application of other pesticides may result in drift for several miles away from the site of the spray operation (Akesson and Yates, undated; Maybank et al., 1978).

(b) Contamination of Surface Waters

Application of silvex to rice fields may result in contamination of rivers and streams. Rice fields are flooded with well water 2 to 4 inches deep and maintained at this level until harvest, except when producers drain their fields for an application of fertilizer in the middle of the growing season. About two weeks before harvest, the water is diverted from the fields to ditches which eventually enter streams and rivers. Silvex contamination of these waters is demonstrated by data retrieved from the STORET system which indicate that silvex residues are present in surface waters throughout the Delta region. It is noted, however, that the monitoring programs do not distinquish between silvex residues originating from rice, pasture and rights-of-way uses in these areas.

In the Delta Region, surface waters are a source of commercial and sport fishing. Although well water is recommended for catfish confinement operations, surface water is sometimes impounded. As a result, some of the fish harvested annually in this region may be cultivated in water contaminated with silvex. This practice creates an opportunity for exposure to the local population which consumes much of the catfish harvested each year. Estimates indicate that the average person in the Delta Region consumes 2.8 kilograms of freshwater catfish, mostly from local sources, each year.

Because surface waters in this area are used for local fish cultivation, the Agency has considered these waters as a possible source of human exposure to silvex. However, in rice-growing areas of Mississippi and Arkansas, the majority of the population obtain drinking water from deep wells and the exposure of these populations would be greater if the ground water also is contaminated. However, because silvex has a half-life in water of about 2 weeks, and TCDD residues, though stable, are relatively immobile in soil, the Agency assumes that contamination of ground water from the rice use is generally unlikely.

(2) Exposure due to Silvex Use on Rangeland

(a) Use Practices and Populations Exposed

Silvex is used on rangeland throughout the country but major usage occurs in Arizona, Arkansas, Kansas, Missouri, New Mexico, Oklahoma, and Texas where about 1.6 million acres of rangeland are treated annually with 2,4,5-T and/or silvex. Estimates indicate that 47,000 people reside within 1/4 mile of the treated areas. Rural population density is generally 3 to 4 people/sq mi with one exception of 16 people/sq mi. in central Missouri.

Generally, silvex is applied by fixed-wing aircraft which fly at speeds of 85 to 105 mph, 10 ft above vegetation in winds that do not exceed 10 mph. The average spray droplet size is 300 microns, and drift control agents are used to reduce spray drift in 50% of the applications. Ground rigs and backpack spray units are used to treat small areas or especially troublesome areas. Applicators set their equipment to deliver droplet sizes ranging from 200 to 300 microns. Estimates indicate that up to 6% of the spray would be 100 microns or less, the particle size most likely to drift significant distances from the target area when these methods are used to apply silvex (Akesson and Yates, Undated).

The amount and formulation of silvex used depends on the kind of vegetation being treated and the density of the growth in the area (see Table 5). Both amine and low volatile ester formulations of 2,4,5-T and silvex are used, frequently in emulsions of water and oil during the spring and summer.

Rates of 0.5 to 2.0 pounds a.i./acre, in 1 to 4 gal/acre volumes are used, but 2 gal/acre volumes are used by 50% of the applicators. Average droplet size is 300 microns, and half of the applications are made with drift control agents. Treatment schedules vary from 1 to 3 consecutive years, depending on the severity of the problem, followed by retreatment 5 or more years later depending on the need.

(b) Water and Soil Residues

The STORET system contains data which show silvex residues in water and sediment in the major rangeland use areas, and residues of silvex have been reported in several Western streams during monthly monitoring for chemical residues at USGS stations. However, because silvex may also have been used on rights-of-way, ditch banks, pastures or aquatic sites in the localities where the residues were detected, it has not been determined if rangeland use of silvex is the source of these residues. The National Surface Water Monitoring Program for Pesticides has not detected levels of silvex in surface water in rangeland use areas.

Studies by Leng (1972) indicate that silvex residues in rangeland decline during the first few months after application. For example, residues of silvex on soil or grasses immediately after application of 0.5 to 1.0 a.i./acre range from 27 ppm to 199 ppm but decline to 0 after 16 weeks. The hydrolytic half-life for silvex has been estimated to be about 14 days (Altom, 1973). The half-life of TCDD residues is estimated to be one year in soil, but TCDD residues were not found deeper than 6 inches below the soil surface (Isensee and Jones, 1971).

Table 5. 2,4,5-T/Silvex Application Rates on Rangeland by Different Treatment Methods

Application Site	Application Method	Region Applied	Application Rate	Number of Applications
Mesquite	Aerial	South Texas Plains	0.67 pounds acid equivalent per acre	3 consecutive seasons; retreatment in 16 years
		Rolling Plains of Texas and Oklahoma	0.5 pounds a.e./acre	one application; retreatment in 8 years
		Rolling Plains of Texas and New Mexico	0.5 pounds a.e./acre	one application; retreatment in 10 years
		Gulf Coast and Coastal Prairie	1 pound a.e./acre	one application; retreatment in 5 years
		South Texas Plains	1 pound a.e./acre	one application; retreatment in 5 years
			2 pounds a.e./acre of 2,4,5-T + picloram (50:50)	one application; retreatment in 5 years
		Southwest	0.5 pounds a.e./acre	one application; retreatment in 10 years
Post and Blackjack Oak Savannah	Aerial		2 pounds a.e./acre	one application; retreatment in 5 years
			2 pounds a.e/acre 1st year & 1.5 to 2 pounds a.e. per acre 2nd year	one application; retreatment in 10 years

Table 5. Continued Methods

Application Site	Application Method	Region Applied	Application Rate	Number of Applications
Hardwoods within Post and Blackjack Oak Savannahs	Aerial		2 pounds a.e./acre	for 2 seasons; retreatment in 10 years
Sand Shinnery Oak			0.5 pounds a.e./acre	for 2 seasons; retreatment in 10 years
			0.5 pounds a.e./acre	one application; retreatment in 5 years
Cactus			2 pounds a.e./acre	retreatment in 20 years
Yucca			0.67 pounds a.e./acre	retreatment in 10 to 15 years
Mesquite and Oak	Broadcast Ground Application		2 pounds a.e./acre	one application; retreatment frequency varies from 5 to 10 years
Yucca			0.67 pounds a.e./acre	one application; retreatment in 10 to 15 years
Mesquite, Oaks, and other species	Spot Treatment		8 to 16 pounds aehg oil for bark treatment, or 6 to 8 pounds aehg water-oil emulsions for basal-stem treatments	

(3) Exposure due to Silvex Use on Apples

Approximately 52,000 acres (10%) of apples are treated annually with silvex to control preharvest fruit drop and to enhance fruit color(Melster, 1977). An estimated 2,500 pounds of silvex active ingredient (ai) is used mainly to treat Red Delicious apples. This accounts for 35% of the 520,000 acres of apple production in the United States. The major areas producing this variety of apple are Washington (55%), North Carolinia (6%), New York (4%), Virginia (4%), Oregon (3%), and Michigan (3%) All other states producing this variety of apple account for 21% of the annual crop.

Silveramine, the triethanolamine salt of silvex is the formulation used on apples. The application rate generally used is 3/4 pint/acre in 300 gallons of water (0.8 ai./acre) applied aerially and by ground rigs.

The impact of spray drift on the population that resides in the vicinity of apple orchards has not been determined but the impact of the extent of possible spray drift can be estimated from other studies. Spray drift during aerial application has been shown to be dependent on the spray equipment used, hydrolic pressure, air turbulence, and the prevailing wind speed. Spray droplets can drift many miles away from the site of application (Akesson and Yates, undated). Drift estimates for ground rig appication of 2,4-D have been calculated experimentally. Estimates indicate that there is a potential for up to 8.0% of the spray to drift at least as far as 5 meters away from the target site depending on the spray equipment used, hydrolic pressure, and the prevailing wind speed (Maybank et al., 1978).

The number of people who reside or work in the vicinity of orchards who may be subjected to spray drift has not been assessed. Moreover, apples are harvested by hand which may result in exposure to farm workers during the harvest season. There is little information regarding the persistence of silvex and TCDD residues on this food source, and the related question of exposure to persons who harvest and handle the crop. However, the need for pertinent data regarding potential exposure to silvex and TCDD is underscored by the finding of an average 0.036 ppm silvex residues in unwashed apples several months after harvest (Cochrane et al., 1976).

(4) Exposure due to Silvex Use on Pears

Silvex is registered for use on Anjou pear trees immediately after harvest to improve fruit set for the following year. It is used on an estimated 600 to 700 acres annually, primarily in Oregon and Washington.

The triethanolamine silvex formulation is applied at a rate of one ounce silvex [11.4 grams (a.i.)] in 70 gallons of water/acre by ground rigs.

The extent of exposure to farm workers and the population in the vicinity of these orchards has not been assessed, but a study conducted with a ground rig application of 2,4-D indicates that as much as 8.0% of the spray may drift at least as far as 5 meters away from the site of application (Maybank et al., 1978). Measurements to determine drift beyond 5 meters were not made. The impact of this potential spray drift has not been determined.

(5) Exposure from Silvex Use on Plums

Approximately 8,300 acres (9%) of the 93,638 acres of plums (for use as prunes) are cultivated annually are treated with silvex. Most of the usage, estimated at 400 pounds active ingredients (a.i), occurs in Oregon (7,407 acres), Washington (1,940 acres), and Idaho (978 acres) where the Italian and Early Italian varieties comprise the greatest percentage of plum acreage in the United States.and account for approximately 11% of the annual prune harvest

Ground rigs are used to apply silvex to virtually all of the plums that are cultivated in these three states. The triethanolamine salt is the only formulation used to prevent fruit drop in plums. The Agency estimates that silvex is applied at the rate of 0.8 ounces (a.i.)/acre of silvex trietanolamine salt. While information regarding the impact of silvex drift away from this use site is lacking, drift estimates for ground rig application of 2,4-D have been calculated experimentally. Estimates indicate that there is a potential as much as 8.0 of the spray to drift 5 meters away from the target site depending on the spray equipment used, hydrolic pressure, and the prevailing wind speed (Mayback et al., 1978).

There is a substantial need for data regarding the extent of silvex and TCDD exposure due to the use of silvex on plums. The population in the vicinity of the major use areas that may be subjected to spray drift from ground rigs has not been estimated. Moreover, neither the extent of exposure to applicators or farm workers during spraying or harvesting nor the persistence of silvex and TCDD residues on plums has been investigated.

(6) Exposure due to Silvex Use on Sugarcane

Silvex is used annually on approximately 115,000 to 230,000 acres of sugarcane primarily for contol of weeds that are resistant to 2,4-D on an estimated 30,000 acres (10%) in Florida and on approximately 85,000 to 200,000 (30 to 65%) acres (63%) of the sugarcane grown in Louisiana. Silvex is applied mainly by aerial application when the cane is less than 3 1/2 feet tall in Louisiana. In contrast, silvex is usually applied by ground rigs in Florida for pre-emergent weed control when seeds are expected to germinate or immediately after the crop bed has been shaped.

The most common silvex formulations used are the low volatile esters which are applied at the rate of 0.75 to 1.0 pounds active ingredients (a.i.)/acre in 10 to 15 gallons of water/acre for both pre-emergent and post-emergent weed control.

The impact of spray drift on the population that resides in the vicinity of sugarcane fields has not been determined but the impact of the extent of possible spray drift can be estimated from other studies. Spray drift during aerial application has been shown to be dependent on the spray equipment used, hydrolic pressure, air turbulence, and the prevailing wind speed. Spray droplets can drift many miles away from the site of application (Akesson and Yates, undated). Drift estimates for ground rig appication of 2,4-D have been calculated experimentally. Estimates indicate that there is a potential for up to 8.0% of the spray to drift at least 5 meters away from the target site depending on the spray equipment used, hydrolic pressure, and the prevailing wind speed (Maybank et al., 1978). Therefore, when the use of the pesticide results in drift in these areas of human work and habitation, people who live and work in the path of the drift may be directly exposed to the pesticide by inhalation and/or by dermal exposure to pesticide droplets in the airborn drift. Moreover, there is little information regarding the persistence of silvex and TCDD residues on this food source, and the related question of exposure to persons who harvest and handle the crop.

Data retrieved from the STORET System for both of these sugarcane growing areas indicates the presence of silvex residues in both surface water and sediment. However, because silvex was used on other sites in the sugarcane growing areas, it has not been determined whether these residues orginated from silvex sugarcane use.

(7) Exposure due to Silvex Use on Non-crop Sites

Silvex is used to treat many broadleaf, herbaceous, and that may be present in a variety of urban and rural non-crop areas such as hedgerows, storage areas, and vacant lots. Recent data regarding the extent of silvex used for these purposes is unavailable. However, data is available from a 1974 report which indicated that approximately 60,000 pounds active ingredient (a.i.) of silvex was used annually for general maintenance of grounds at industrial, commercial and institutional sites. Presently, the Agency has no better estimate of how much silvex is used for non-crop areas (EPA, 1978).

Silvex is used throughout the country for this kind of weed control. The most common formulations are the low volatile silvex esters which are frequently formulated with 2,4-D or Dicamba for a broad spectrum of weed control action. Ground rigs are used to treat large areas but hand held application devices are frequently used for spot treatments in small areas. The Agency has no estimate of the number of people that use silvex or the number of people in the immediate vicinity of these spray sites because of their heterogeneous nature.

Exposure for this kind of usage appears to be confined to the applicator and those people residing or working in the immediate vicinity of the spray area. Information from studies of forest workers who apply phenoxy-herbicides with backpack sprayers indicates that it may be possible for the applicator to contact 0.8 ppb of the chemical spray due to dermal exposre and 0.3 ppb due to inhalation exposure (Lavy, 1978). Therefore, the Agency is concerned about the exposure that may result due to direct contact as well as drift.

C. Epidemiologic Data

The risk assessment for silvex is based in part on data showing that exposure to silvex and/or TCDD results in tumors, and dead and deformed offspring in test animals, and that the uses of the pesticide create opportunities for exposure to humans. Together these facts suggest that if the use of the pesticide results in human exposure, humans who live and work in areas of use may experience the kinds of adverse health effects observed in test animals.

This reasoning is borne out by the results of a recent epidemiological study which reported that women living in the vicinity of Alsea, Oregon have a statistically significant higher incidence of spontaneous abortions (miscarriages) than women living in a control area. Alsea is an area in which two dioxin-containing pesticides, 2,4,5-T and silvex are used extensively for forest management and on rights of way. Additional analyses of the data indicate that there is a significant correlation between the use of 2,4,5-T in the study area and the subsequent increase in the rate of spontaneous abortions in the study area.[*/]

[*/] The Alsea study was analyzed using only 2,4,5-T data. However, the serious implications of this study are as applicable to silvex as to 2,4,5-T, because TCDD, the contaminant contained in both herbicides, is a potent mammalian fetotoxin and teratogen at very low doses. Conversely, silvex and 2,4,5-T are fetotoxic and teratogenic at comparatively higher doses. It is reasonable to assume that the adverse human reproductive effects observed in Alsea, which have been attributed to low-level exposure to 2,4,5-T, are due primarily, or at least in part, to the TCDD in the 2,4,5-T. Therefore, since silvex also contains TCDD, it is prudent to conclude that the Alsea data are applicable to silvex use when evaluating potential reproductive risk to humans. See 44 FR 15904.

This relationship between exposure to TCDD-containing phenoxy herbicides and an increased incidence of miscarriages in humans is not surprising. This is the same relationship that has been demonstrated to exist in test animals through numerous animal studies. While there are uncertainties concerning the amount of phenoxy herbicide and/or TCDD to which the Alsea area women may have been exposed and concerning the precise route (or routes) of human exposure, the statistically significant incidence of miscarriages described above, coupled with the uncontestable data from the animal studies, makes it reasonable to conclude that women in the Alsea study area may be exposed to, and adversely affected by 2,4,5-T, silvex and/or TCDD. Moreover, it is also reasonable to assume that the same type of effects may occur wherever and whenever 2,4,5-T or silvex containing TCDD is used.

Further, the Alsea experience may not be an isolated incident. Reports of people adversely affected by exposure to phenoxy herbicides and/or TCDD have frequently appeared in medical and scientific journals. Recent summaries appear in IARC, NRCC, and U.S. Air Force documents on phenoxy herbicides and dioxins. In addition, as a result of the 2,4,5-T RPAR, the Agency has received numerous accounts of adverse human health effects which the reporters attributed to phenoxy herbicides and/or TCDD. The cumulative effect of these reported incidents suggests that people who live and/or work in areas of silvex use may experience adverse health effects.

III. Preliminary Benefits Analysis of Silvex use on Range, Rice, Orchards, Sugarcane and Non-crop Areas.

A. Introduction

This preliminary analysis is an assessment of the economic impact of the cancellation of silvex for use on range, rice, orchards, sugarcane, and non-crop areas. The analysis assumes that 2,4,5-T also will be cancelled for these uses. In view of the virtually identical toxicological characteristics of the two compounds and the similarity of the benefits of both, it is unlikely that only one of them would be cancelled.

The information, relating to the benefits of silvex, used in this report was derived principally from a single source - The Biologic and Economic Assessment of 2,4,5-T ("USDA Assessment Report").[*] Also under this memorandum, a joint USDA-States-EPA Silvex Assessment Team was formed to provide benefits information on silvex. The economic analyses for the sugarcane and orchard uses of silvex are based on preliminary information partially provided by members of the Silvex Assessment Team.

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[*] This report was prepared jointly by the USDA-States-EPA 2,4,5-T Assessment Team, established pursuant to a memorandum of understanding between USDA and EPA.

There are disadvantages to the heavy reliance of this analysis upon the 2,4,5-T Assessment Report for the range and rice information. As is commonly the case in assessing benefits of pesticides, the available information reported in the USDA Assessment Report was a mixture of empirical data and expert opinion and did not lend itself to precise statistical analysis. Thus, the estimates reported in this analysis represent rough predictions of the impact of cancellation. The lack of confidence intervals or error terms does not imply exact precision. The estimates are merely approximations of the projected impacts within the limitations of the data and analyses.**/

The general approach of this analysis is to evaluate the economic impacts arising from users' shifting to alternatives to silvex (other than 2,4,5-T) where alternatives are available and, where no alternatives are available, economic impacts on users and at the commodity and consumer levels are projected based on crop yield reduction and possible user shifts to other crops then projecting these impacts at the commodity and consumer levels where appropriate. Impacts on users are considered on a per-unit, per-establishment basis and at the state, regional, and national levels.

**/ The Agency is continuing to collect and review data relating to the benefits of silvex use for range, rice, orchards, sugarcane and non-crop areas.

(B) Summary of Findings

(1) Rangeland***/

There are an estimated one billion acres of range and pasture land suitable for grazing in the contiguous 48 states, plus 351 million acres in Alaska and 3 million acres in Hawaii. About 90 percent of this total acreage is rangeland. Of this total, approximately one percent is treated with herbicides, primarily 2,4-D. Only about 150,000 acres, or less than 0.1% of range acres, are treated with silvex.

Silvex is used to control various woody and herbaceous plants found in rangeland. Most silvex use is directed at control of various oak species which compete with desirable forage plants for water, nutrients, sunlight and space. Treatment is generally directed at acreage with severe infestation which, if left uncontrolled, would reduce forage available for livestock grazing.

A number of chemical and non-chemical alternatives to silvex are available to control the various weeds now

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***/ "Rangeland" is defined as land producing forage for animal consumption, harvested by grazing, which is not cultivated, seeded, fertilized, irrigated or treated with pesticides or other such similar practices on an annual basis. Fencerows enclosing range areas are included as part of the range.

treated with silvex. However, none of these alternatives is effective against oaks when applied aerially. Thus, effective substitute treatments for silvex must be applied by ground techniques which are more expensive and less convenient. The availability of alternatives and the very small quantity of acreage involved indicate that no significant economic impacts will be felt at either the consumer or market levels if silvex is cancelled for this use. At the user level, some increased control costs and decreased production may be experienced by a small number of users. In some locations, the impact on users may be significant.

(2) Rice

Although about 98% of all U.S. rice areas are treated with one or more herbicides, silvex is used on only 2,000 acres annually, or less than 0.1% of all U.S. rice acres. In those areas where silvex is used, it is employed to control various broadleaf, aquatic and sedge weeds. These weeds, if not controlled, reduce yield and lower the quality of the rice by contaminating the harvested grain with weed seeds.

There are several chemical alternatives which are likely to be employed as substitutes for silvex use on rice. These compounds may be somewhat less effective and/or more expensive than silvex for use on some weeds. Therefore, some degree of increased control costs and reduced production may be experienced on some acres as a result of the substitution of these materials for silvex. However, because silvex is used on so little rice-growing acreage, the economic impact at the user, consumer and market levels will be quite small if silvex were cancelled for this use.

(3) Orchard

Silvex is used on apples and prunes to control preharvest fruit drop and on pears to increase fruit set. Premature drops cause a complete economic loss of prunes and a substantial loss of apple crops. Approximately 50,000 acres of apples (10% of U.S. crop) are treated annually with about 2,500 pounds of silvex. Most of the treated apples are Red Delicious, grown in Washington and several other states, which are sold for fresh consumption. About 8,300 acres of Italian prunes (9% of U.S. acres) grown in Oregon, Washington, and Idaho are treated with about 400 pounds of silvex annually. Treated prunes are believed to be sold primarily for fresh consumption. The extent of silvex usage on pears is unknown.

NAA (1-napthaleneacetic acid) and Alar (succinic acid 2,2-dimethyl hydrazine) probably would be used by apple growers as chemical alternatives to silvex. Some acres would require two annual treatments with these materials for effective control, whereas use of silvex requires only one treatment. The economic impact is likely to consist of higher costs to apple growers, totaling approximately $1 million per year or $20 per average affected acre, resulting from the use of these alternatives. The higher drop control costs will increase production costs by 2-3% per year. Apple production and quality should not be significantly affected.

Prune growers currently using silvex would suffer significant income reductions if silvex is unavailable. Italian and early Italian prunes in the Northwest states drop an average of 35% of the fruit if silvex is not applied in mid-June to control summer drop. Since there are no registered alternatives to silvex for this use, production and revenues would decline sharply on the affected acres. Revenue reductions totaling $1.8 million annually, or about $222 per affected acre, are projected to occur, assuming no alternatives to silvex are developed to prevent preharvest drop. Continued losses of this magnitude would eventually cause growers to grow alternative crops on the estimated 8,300 acres of prunes for which preharvest drop problems are significant.

The retail price of apples and pears would probably be unaffected by cancellation of silvex for orchard use. The retail price of prunes would increase by an undetermined amount.

(4) Sugarcane

Silvex is used on sugarcane fields to control weeds not controlled by 2,4-D. Failure to control these weeds can result in reduced yields. About 15% (115,000 acres) of all U.S. sugarcane acres (752,000 acres) were treated with silvex in 1978. This reflects a significant decrease in silvex use over previous years, probably resulting from increased use of an alternative dicamba /2,4-D mixture. The dicamba / 2,4-D combination alternative is likely to be the most commonly used substitute if silvex is canceled for use on sugarcane. Economic impacts arising from a cancellation of silvex would result from reduced yield, which would occur because the alternative is less efffective than silvex . A worst-case estimate indicates a 2% loss of overall U.S. sugarcane production could be experienced. Since U.S. - produced cane sugar comprises only 18% of the total U.S. sugar supply, no measurable sugar price changes are likely to occur at either the market or consumer levels.

(5) Non-Crop Uses*/

Silvex is registered for control of many broadleaved and herbaceous weeds in a variety of urban and rural non-crop areas such as fencerows, storage areas and parking lots. Only a very small percentage of non-crop areas is treated with silvex each year.

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*/"Non-crop areas" includes: fencerows, hedgerows, fences (not otherwise included among previously suspended uses, e.g. rights-of-way, pasture); industrial sites or buildings (not other wise included among previously suspended uses, e.g. rights-of-way, commercial/ornamental turf); storage areas, waste areas, vacant and parking lots.

Both chemical and non-chemical controls are available as alternatives to silvex for use on non-crop areas. The chemical alternatives include 2,4-D, picloram, dicamba, AMS, amitrole. Non-chemical controls include mechanical methods such as mowing, shearing, and manual methods. The relative efficacy of the alternatives in comparsion to silvex is unknown. However, it is believed that one or a combination of the chemical alternatives will be widely substituted for silvex and will provide equivalent control.

The economic impact of cancelling silvex for non-crop uses is not likely to be significant at user, consumer or market levels because little acreage is treated with silvex and effective alternatives are readily available.

(C) General Production and Use Pattern

Silvex is produced domestically by The Dow Chemical Company, Thompson-Hayward Chemical Company, Transvaal Inc., and Vertac Inc. Domestic use of silvex is estimated to be about 3.0 million pounds acid equivalent (a.e.) annually. The use of silvex on range and rice comprises almost 7.0% (202,000 pounds a.e.) of the estimated 3.0 million pounds a.e. used annually. Rangeland usage accounts for 6.7% (200,000 pounds a.e.) of this amount, and use on rice accounts for 0.1% (2,000 pounds a.e.). Reliable use information for orchard uses is not available. Silvex is used on approximately 100,000 acres of rangeland and 2,000 acres of rice annually. This acreage amounts to about 0.01 percent of the total U.S. range acreage and 0.08% of total U.S. rice acreage.

(D) Preliminary Benefits Analysis of Silvex Use on Range land*/

(1) Current Use

A wide variety of herbaceous and woody plants grow on rangelands. Several weed species controlled with silvex such as yucca, salt cedar and various oak species, compete with the desired forage species for nutrients, water, space and light. Serious infestations of range weeds can significantly reduce forage available for grazing and thus reduce livestock production on the infested acres.

Silvex is not a major range weed herbicide. Its use has been limited because 2,4,5-T is slightly less expensive and controls a broader spectrum of weeds. Of the 900 million acres of range in the U.S., only about 150,000 acres are treated with silvex annually. Silvex is used primarily to control several oak species, almost exclusively in Texas, New Mexico, Arkansas, Oklahoma, Kansas, and Missouri.

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*/ "Rangeland" is defined as land producing forage for animal consumption, harvested by grazing, which is not cultivated, seeded, fertilized, irrigated or treated with pesticides or other such similar practices on an annual basis. Fencerows enclosing range areas are included as part of the range.

This analysis evaluates only aerial application for the control of oak species; such applications are believed to account for the majority of silvex range treatments.

(2) Evaluation of Silvex and Alternatives

Silvex provides good control of several oak species for periods of 5-10 years per application. Several registered chemical alternatives as well as non-chemical controls not analyzed here are effective against one or more of the various range weeds controlled by silvex. However, these chemicals are either not registered for aerial application or are not as effective as silvex for aerial application. For example, 2,4-D and dicamba can be applied aerially, to rangeland, as foliar sprays, but they are relatively ineffective as foliar sprays. The USDA Assessment Team concluded that there is no effective alternative for aerial spray control of oaks. For situations where ground applications, especially spot treatment, are practical, the chemical alternatives may provide effective control, depending on the nature and complexity of the weed problem.

Assuming there are no alternatives to aerially applied silvex for oak control, the yield effects could be severe on acreage currently treated with silvex. Cancellation would leave users with no aerially applied alternative control for oak on these acres. In the post-blackjack oak area, beef yields could fall from about 28 pounds of beef (live weight) per acre with silvex control to 11 pounds of beef (live weight) per acre for calf production and from about 84 to 45 pounds per acre for steer production. In the sand-shinnery oak area beef yield could decline from about 27 to 14 pounds per acre following a shift from silvex to no-control.

(3) Economic Impact

Current silvex use appears to be limited primarily to control of various oak species by aerial application. If silvex is cancelled for this use most users will probably choose not to treat large areas formerly treated with silvex because of the absence of a practical and efficacious aerially applied control agent. These users will save from $4.60 to $13.00 per acre in control costs. However, this savings will be offset by lower revenues from lower beef production. Those silvex users who need only spot treatments will be able to obtain at least some control with one or more of the various alternatives now available.*/ The aggregate impact on users will be small because of the small acreage involved.

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*/ In addition to the chemical alternatives now registered for range use, several promising herbicides are under review; this analysis does not attempt to estimate the impact of these or other possible new alternatives.

The cancellation of silvex for range weed control will not have significant economic impacts at either the consumer or market levels, since few rangeland acres are currently treated.

E. Preliminary Benefits Analysis of Silvex Use on Rice

(1) Current Use

Conditions favorable for growing rice also favor the growth and reproduction of many terrestrial, aquatic, and semi-aquatic weeds. Weeds in rice-growing areas produce an abundance of seed. Once these infest the land, they are difficult to remove and may remain viable in the soil for many years. Rice weeds reduce yields by direct competition and reduce quality through contamination of the harvested rice with weed seeds.

The total estimated direct losses and expenditures for weed control in U.S. rice acreage were $295 million annually for the 1975-1977 period. Weeds reduce the yield and quality of rice in the U.S. by an estimated 15 percent each year on approximately 2.5 million acres. The average loss was valued at about $165 million annually during the 1975-1977 period. The cost of using all herbicides on rice acreage was about $60 million each year during the same period. The cost of cultural practices (including rotation, land preparation, irrigation, and fertilization) during this period was estimated at $70 million.

Silvex is useful for controlling certain weed pests, but it is injurious to soybeans, an important crop grown in rotation with rice. Silvex is used annually on only 2,000 rice-growing acres, primarily in the lower Mississippi Valley area. The average annual cost of silvex for use on these 2,000 acres for 1975-1977 was approximately $20,000.

Propanil and molinate are the herbicides used most heavily on rice acreage. Combined, these chemicals account for 73% of herbicide acre-applications to rice. Each of these compounds controls some of the weeds controlled by silvex and is likely to be used to replace silvex on some acres now treated with silvex. In addition, 2,4-D, MCPA, bifenox, bentazon and oxadiazon are all currently used on rice and will control various combinations of weeds currently controlled by silvex.

Cultural and mechanical weed control methods used in rice production include summer fallowing, seedbed preparation, crop rotation, special seeding methods, management of irrigation water, cultivation and hand weeding (in sparse weed infestations or in small isolated areas). Although some of these methods are effective alone on some rice weeds, they are usually combined with chemical herbicide treatments.

(2) Evaluation of Silvex and Alternatives

Silvex controls most broadleaf, aquatic and sedge weeds more effectively than the registered chemical alternatives. However, silvex is very injurious to soybeans, a crop commonly grown in rotation with rice. In addition, silvex is also damaging to cotton, a crop often grown near rice fields.

Propanil is currently applied to about 95% of the rice acres in the lower Mississippi Valley area for early season control of grasses. Propanil selectively kills barnyard grass and many other grass, aquatic, broadleaf and sedge weeds. At maximum label rates (8 lbs/acre/season) propanil alone is said to often fail to provide adequate control of the total weed population. Propanil controls hemp sesbania as effectively as silvex. However, northern jointvetch, ducksalad, and redstem are only partially controlled by propanil. 2,4-D is thought to be comparable to silvex in controlling most broadleaf, aquatic and sedge weeds. It is not as effective as silvex for control of northern jointvetch, and grass weeds. Its use is restricted somewhat by most rice growing states because it is highly injurious to cotton.

Several other herbicides used for control of rice weeds include molinate, MCPA, bifenox, bentazon and oxadiazon.

Molinate does not effectively control hemp sesbania,northern jointvetch, ducksalad, morningglory or redstem. MCPA is not used in the silvex use area since it is relatively ineffective on hemp sesbania, northern jointvetch, and Indian jointvetch. Bifenox, bentazon, and oxadiazon are three new herbicides which are currently used to a limited extent. They are not as effective as silvex on most broadleaf and aquatic weeds.

If silvex were canceled for use on rice, current silvex users probably would turn to alternative chemical controls. 2,4-D and propanil would be the most likely alternatives. Use of these alternatives would cost $7.40 per acre-treatment for 2,4-D and $12.90 per acre-treatment for propanil compared with $9.50 per acre-treatment for silvex. Use of propanil may require a second treatment, thus raising the annual cost of control to $21.80 per acre.

(3) Economic Impact

Silvex is used on only 2,000 rice-growing acres in the U.S. There are several alternative controls available which will function adequately as substitutes for silvex. For these reasons, economic impacts are not expected to be significant at user, consumer or market levels.

F. Preliminary Benefits Analysis of Silvex Use in Orchards

(1) Current Use

Silvex is registered for use in preventing preharvest fruit drop of apples and prunes and to increase the yield of pears.

Prunes that drop from trees prematurely cannot be put to any commercial use; apples that drop prematurely can, in some cases, be sold for low-return uses, such as cider.

On apples, silvex applications are generally made using ground equipment a few days before preharvest drop would normally occur. Ordinarily, the application takes place one to two weeks prior to the expected peak of harvest for a given apple variety, and one application controls drop for several weeks (through harvest). Both the timing and application rate of the silvex spray vary according to the cultivar involved.

In addition to minimizing preharvest apple drop and thus increasing aggregate production, silvex also acts to increase the quality of treated fruit. The extra one to two weeks of on-tree ripening of fruit facilitated by the use of silvex tends to improve the color, sugar content and flavor of the sprayed fruit. These chacteristics are particularly important for fresh-market growers[*].

Silvex use on certain prune varieties in the Northwest is of major importance. Silvex is used in the production of Italian and Early Italian prunes in Oregon, Washington and Idaho. It is believed that silvex applications prevent an average 30% drop rate which would otherwise occur. Silvex is also used on about 700 acres of Anjou pears in Oregon and Washington to increase fruit set in the year following application. The use of silvex for this purpose is not recommended by either state.

Very little quantitative data are available indicating the specific location and/or extent of silvex use on apples or prunes. Information for this analysis was developed through discussions with horticultural specialists. Based on these discussions, it is estimated that approximately 50,000 acres of U.S. apples (10% of U.S. apple acreage) are treated annually with silvex */

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[*] The majority of the silvex used on apples is probably applied to Red Delicious, the leading apple variety which accounted for 35% of U.S. apple production in 1977. The major Red Delicious producing states, ranked in order of 1977 production, are as follows: Washington (55% of U.S. Red Delicious crop), North Carolina (5%), California (5%), New York (4%), Virginia (4%), Oregon (3%), Michigan (3%), all other states (21%). Small quantities of silvex are also applied to other apple cultivars susceptible to pre-harvest drop, including Jonathan, Rome Beauty, and Stayman.

Silvex use on prunes is probably restricted to Italian and Early Italian varieties in the Northwest states (Oregon, Washington, Idaho).**/ Recent estimates indicate that about 80% and 100%, respectively, of Washington and Idaho prunes are treated annually with silvex. The extent of silvex use on pears is not known.

(2) Evaluation of Silvex and Alternatives

Currently, two alternatives to silvex are available for use on apples to control preharvest drop. NAA (1-napthaleneacetic acid) is registered for apples both as an early season thinning agent and as a late season drop control agent. NAA may be applied at the rate of 35 grams of active

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*/ The quantity of silvex required to treat 50,000 acres of apples per year was derived based on the following assumptions:

material used: triethanolamine salt of silvex 9.6% equivalent to 6.2% silvex by weight or 8.5 ounces a.i. per gallon.

application rate: 1/4 pint/100 gallons water, 300 gallons water/acre; 3/4 pint/acre x 1.063 ounces a.i./pint = .8 ounces a.i./acre.

quantity a.i. used: 50,000 acres treated x .8 ounces a.i./acre = 2,500 pounds silvex a.i.

**/ Prune acreage in the affected states is as follows:

Oregon	7,407 acres
Washington	1,940 acres
Idaho	978 acres
	10,325 acres

ingredient per acre via air or ground to control premature drop; application is made 7 to 14 days before harvest. Alar (succinic acid 2,2-dimethyl hydrazide) is registered for premature drop control at the rate of 6.8 pounds of active ingredient per acre.

Silvex is believed to be effective in preventing apples from dropping prematurely. However, quantitative data indicating the amount of drop actually prevented are not available. It is believed that silvex is a preferable drop control agent in many areas because of its relatively long period of effectiveness (3 to 4 weeks in the East, up to 5 to 6 weeks in the West).

NAA and Alar would have increased usage on apples if silvex were unavailable, but they are thought to be somewhat less effective than silvex. NAA is less effective in the southern apple states and is best suited for varieties other than Red Delicious. NAA's period of effectiveness is shorter than silvex's; a second application may be needed in some cases. Alar is a major alternative to silvex on apples since it is suitable for use on Red Delicious. However, Alar is believed to be less effective than silvex for preharvest drop control and may reduce fruit size. Alar may also cause undesirable changes in fruit shape the following year if applied within 60 days of harvest. Alar may be applied from 10 to 70 days after full bloom but is usually applied from 50 to 70 days following bloom to minimize the adverse fruit size effects. Thus, use of Alar as a silvex alternative would necessitate a carefully timed spray schedule and would result in somewhat lower preharvest drop effectiveness.

Silvex treatment of prunes is believed to result in retention of approximately 95% of the fruit until harvest. Silvex use on prunes is particularly useful during years when cool but not frosty conditions occur in the spring, resulting in a particularly light fruit set. Without silvex, as much as 50% of the Early Italian prunes and about 22.5% of the standard Italian prunes in the northwest states would be lost due to premature fruit drop.

There are currently no registered alternatives to silvex for premature drop control on prunes. However, 2,4-DP (currently registered for some non-crop applications) reportedly has provided good prune drop control in field tests. There are no registered alternatives for silvex use on pears.

There is no indication that non-chemical controls are effective in preventing preharvest drop of apples or prunes.

(3) Economic Impact

(a) General Considerations

Since apples and prunes are permanent, capital-intensive crops, the loss of silvex would not cause a shift to other crops but would instead lead to adoption of alternative materials (in the case of apples). Prune growers would be left without a registered preharvest drop control agent and would likely incur some adverse economic impacts. These effects could cause a long-term shift from prunes to other crops.

For apples, it is assumed that all of the estimated acreage currently treated with silvex will be treated with alternatives (Alar and NAA). Due to NAA's shorter effectiveness period relative to silvex's and the disruption in harvesting some NAA-treated orchards which may be expected to occur because of poor weather, labor shortages, and other factors, it is assumed that as much as 25% of the NAA-treated acreage may require an additional application. In addition, since Alar may not provide a level of preharvest drop control equal to that provided by NAA or silvex, an assumption was made that an additional preharvest application of NAA may be required on as much as 25% of the Alar-treated acreage to provide a level of preharvest drop control equal to that provide by silvex.

Although Alar is significantly more expensive to use than NAA, its beneficial effects other than drop control would tend to encourage usage.*/ In the absence of a precise method to determine the relative substitution ratio of Alar and NAA for silvex, this analysis assumes an equal distribution of the two alternatives.

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*/ Alar promotes intensification of color in red cultivars, reduces incidence of water core and vegetative growth, and promotes flower bed formation.

For prunes, the analysis assumes that, as a worst case, the unavailability of silvex will result in an incremental loss in annual production of 30% of the Italian prune crop in Oregon, Washington, and Idaho. This assumption is based on a "normal" (with silvex) preharvest drop of 5% and an "abnormal" (without silvex) loss rate of 35% due to unchecked mid-June drop.

(b) User Impacts

The unavailability of silvex will increase grower preharvest drop control costs for apple growers by about $5.00 (using NAA) or $35.00 (using Alar) per acre-treatment. Although the use of Alar significantly increases preharvest drop control costs, it also provides additional benefits: Alar, like silvex, enhances the quality of the fruit and promotes early-season marketability. Thus, it is reasonable to conclude that Alar would be used by growers as a silvex alternative.

The use of Alar and NAA as silvex alternatives may increase apple grower production costs by as much as about $1 million per year or an average of $20 per affected acre. Since apple production (growing + harvesting) costs range from about $700 - $950 per acre, the projected increase in drop control costs would increase total production costs by from 2-3% per year on the affected acres. Assuming that 50,000 acres of apples are currently treated with silvex per year, the cost impact would occur on about 10% of U.S. apple producers.

Growers of Italian-variety prunes would incur major adverse income impacts if silvex is unavailable. Prune grower impacts were derived as follows:*/

with silvex:

average production per acre:	5 tons
market:	fresh
grower price per ton:	$155
average gross revenue per acre:	$775
average production costs per acre:	$504
net revenue per acre:	$271

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*/This analysis is based on a 3-year (1975-1977) average price for fresh prunes grown in Oregon. Production averages and costs are based on a 1974 budget for Italian prunes grown in the Willamette Valley of Oregon. Costs were adjusted upward by 3% per year to account for inflation during the 1974-1979 period. Costs without silvex were reduced by $10 per acre to account for the lack of treatment expense if silvex is unavailable (treatment costs using silvex on prunes assumed to be the same as those for apples).

without silvex:

average production per acre: 3.5 tons
market: fresh
grower price per ton: $155
average gross revenue per acre: $543
average production costs per acre: $494
net revenue per acre: $49

Reduction in per acre net revenues (from $271 to $49) of this magnitude (82%) due to the lack of preharvest drop control amounts to an aggregate revenue loss of about $1.8 million per year. Revenue losses of this magnitude (assuming the continuing lack of an alternative for silvex) would probably lead growers gradually to replace the Italian prune cultivars with other crops; completion of this process would take several years following cancellation of silvex. Assuming growers would replant the affected acres with other tree fruits, they would incur establishment costs ranging from about $3,000 to $5,000 per acre in current dollars.

Sufficient information to evaluate producer the impact of a cancellation of silvex for use on pears is not available.

(c) Consumer Impacts

The cost increases projected for affected apple growers ($1 million/year) may be absorbed at the grower level since only about 10% of U.S. growers would be directly affected by a restriction on silvex. If the costs were passed on to consumers, the retail price effects would be negligible.

Retail prices for prunes would be expected to increase as supplies dropped, but the extent of such an increase cannot be reliably determined with available data. The estimated 30% reduction in production of Italian prune cultivars in the Northwest would result in production losses of 12,390 tons (8,260 affected acres X 1.5 ton loss per acre), as much as 40% of U.S. fresh prune production (30,700 tons in 1977) and 6% of total U.S. prune production (fresh, processed, and dried prunes; 215,000 tons).

Sufficient information to evaluate the consumer impact of cancellation of silvex for use on pears is not available.

(d) Limitations of Analysis

The foregoing analysis has the following limitations in addition to the limitations common to the economic analysis of the range, rice, non-crop and sugarcane uses of silvex:

(1) Extremely little data are available concerning the extent of silvex use on apples, prunes or pears; and

(2) Information provided by horticultural specialists was used in lieu of quantitative data concerning extent of silvex use and crop yields without silvex.

G. Preliminary Benefits Analysis of Silvex Use on Sugarcane

(1) Current Use of Silvex and Alternatives

Silvex is used in Louisiana and Florida sugarcane fields to control various weeds which have developed resistance to 2,4-D. In Louisiana, these weeds include goldenrod, aster, alligator weed, and various winter annual broadleaves. In Florida, the primary target weed pests are dogfennel, ground cherry, nightshade, and ragweed.

In Louisiana, the principal alternative to silvex is a combination product, consisting of dicamba (1 pound per gallon) and 2,4-D (3 pounds per gallon). Florida does not now have a registration for this combination product. Therefore, 2,4-D is the only currently available alternative to silvex in Florida.

Silvex use has decreased markedly in Louisiana in recent years (Table 1). The decreased levels of silvex in Louisiana have been attributed to shortages of silvex and the lower application costs of the 2,4-D-dicamba combination product. Some of the Louisiana cane growers are likely to shift back from the 2,4-D-dicamba combination product to silvex because of yield losses reportedly experienced with the combination product. In addition, some sugarcane acreage is shifting to soybean production in Louisiana. The 2,4-D-dicamba combination product cannot be used on sugarcane adjacent to soybean fields because it is phytotoxic to soybeans. This is expected to further increase silvex use.

Table 1. Silvex Use on Sugarcane Grown for Sugar and Seed, 1978

¶Location	1976 Harvested	Treated	1977 Harvested	Treated	1978 Harvested	Treated¶
	---------	---------	---------	-1,000 acres-	---------	---------¶
¶Florida	298.0	30.0	300.0	30.0	310.0	30.0 ¶
¶Hawaii	106.7	0	103.5	0	108.3	0 ¶
¶Louisiana	315.0	200.0	322.0	170.0	300.0	85.0 ¶
¶Texas	27.3	0	33.9	0	34.1	0 ¶
¶U.S.*	747.0	230.0	759.4	200.0	752.4	115.0 ¶

*/ Puerto Rico is not included, but silvex use in that location is negligible.

Expert opinion suggests that sugarcane yield loss of less than 10% would occur in Louisiana if the 2,4-D-dicamba combination product were substituted for silvex. In Florida, yield losses of up to a maximum of 30% could occur if 2,4-D were substituted for silvex.

(2) Economic Impact

(a) User Impacts

The economic impacts of the cancellation of silvex to sugarcane producers include changes in weed control costs and potential yield losses in Louisiana and Florida. Herbicide costs would decline in both Louisiana and Florida.

In Louisiana, the substitution of the 2,4-D-dicamba combination product for silvex would reduce chemical costs from $5.00 to $3.50 per acre. In Florida, the substitution of 2,4-D for silvex would reduce chemical costs from about $5.00 to $4.00 per acre. The aggregate decrease in weed control costs is estimated at approximately $260,000 annually (assumes the 1976-1978 average of silvex treated acres).

This saving in herbicide costs will be offset by yield losses and therefore gross revenue losses to sugarcane producers. Yield losses of 25% are expected to result in a loss in value of production of approximately $4.0 million in Florida. Yield losses ranging from 0 to 10 percent could result in losses in value of production as high as $6.3 million in Louisiana.

Aggregate economic impacts to the users of silvex are estimated at approximately $3.8-10.1 million annually. Aggregate losses of $4.0 million ($130 per silvex treated acre) are expected in Florida. In Louisiana, estimated economic impacts range from gains of $0.2 million to losses of $6.1 million (economic impacts ranging from a gain of approximately $1.50 per acre to losses of $40 per silvex treated acre), depending on the level of yield loss (0-10%).

(b) Market and Consumer Impacts

The 1976-1978 average annual sugarcane production exceeded 26 million tons. Production losses of 596,580 tons following a silvex cancellation (assuming a 25% yield loss and a 10% yield loss on silvex treated acreage in Florida and Louisiana, respectively) is approximately 2% of the total U.S. cane production. 1978 U.S. - produced cane sugar represented less than 18% of the U.S. sugar supply. Therefore, the cancellation of silvex is not anticipated to result in measurable sugar price changes at the market or consumer level. Since cane can be sold for either sugar or seed at approximately the same price, measurable price changes are not anticipated in the seed cane market.

H. Preliminary Benefits Analysis of Silvex use on Non-crop Areas[*/]

(1) Current Use

Silvex is registered for control of many broadleaved and herbaceous weeds[**/] in a variety of urban and rural non-crop areas such as fencerows, storage areas and parking lots. Silvex is used because of its relatively low cost, the broad spectrum of weeds it controls and its selectivity for control of undesirable plant species. Generally, the weed control achieved on these sites does not involve major economic benefits.

[*/] "Non-crop areas" includes: fencerows, hedgerows, fences (not otherwise included among previously suspended uses, e.g. rights-of-way, pasture); industrial sites or buildings (not other wise included among previously suspended uses, e.g. rights-of-way, commercial/ornamental turf); storage areas, waste areas, vacant and parking lots.

[**/] Pest weeds include the following broadleaved plants--pigweed, ragweed, lambsquarters horsenettle, cocklebur, morningglory--and woody plants--oaks, poplar, cottonwood, wild cherry, blackberry, honeysuckle, poison ivy, and wild grape.

Recent data on the usage of silvex for noncrop areas is not available. However, a 1974 publication reported that 60,000 lbs. a.e. of silvex were used for general maintenance on 30,000 acres of grounds at industrial, commercial and institutional sites. This area is a small proportion (1.7%) of the 1.8 million acres treated with herbicides for grounds maintenance.

Both chemical and non-chemical controls are available as alternatives to silvex. Chemical alternatives include herbicides, such as 2,4-D, picloram, dicamba, AMS, or amitrole. Probably the most comparable alternatives are combination products, such as 2,4-D + picloram or 2,4-D + dicamba. Soil sterilants, such as sodium borate or sodium chlorate, control weeds that silvex controls but are effective primarily as preventive controls. Subsequent infestations sometimes may require follow-up treatments with conventional herbicides.

Mechanical methods of control, such as mowing or shearing, or manual methods could also serve as alternatives to silvex.

(2) Evaluation of Silvex and Alternatives

The efficacy of the alternatives compared with that of silvex is not known. The spectrum of weeds controlled will differ from that of silvex for the individual active ingredients.

However, silvex's weed spectrum may be approximated fairly closely by using a combination product or by using multiple applications of different herbicides.

Generally, no more than one treatment with silvex is needed annually to achieve control of the problem weeds. In some circumstances, one treatment will give control for up to four years. Combination products with 2,4-D and picloram will give control for a length of time comparable to that provided by silvex, but other herbicides, such as 2,4-D alone or amitrole, may require more than one treatment annually. The length of control with mechanical or manual means is unknown.

(3) Economic Impact

In general, effective alternatives to silvex exist for non-crop sites. Effective alternative combination products which provide equally long term control are registered. Impacts on users of silvex will be felt in the form of increased control costs for the combination alternatives.

Cancellation for the non-crop use of silvex is likely to cause little, if any, economic impact at the market and consumer levels. Effective alternatives are available, and the economic value of weed control on non-crop sites is very small.

IV. REGULATORY DETERMINATION

Section 6(b) of FIFRA provides that the Agency may move to cancel the registration of a pesticide "[i]f it appears to the Administrator that a pesticide... when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." In effect, this "unreasonable adverse effects" standard requires a finding that the risks of each use of the pesticide exceed the benefits of use, when the pesticide is used in accordance with the terms and conditions of registration or in accordance with widespread and commonly recognized practice.

Upon concluding the RPAR review of a pesticide, if the Administrator determines that the risks of use outweigh the benefits of use, he may issue a notice of intent to cancel or deny registration, pursuant to section 6(b)(1) or Section 3(c)(6). If on the other hand, the Administrator determines that the use of the pesticide appears to cause unreasonable adverse effects on the environment, that there are uncertainties in the data relating to the risks and benefits of these uses, and that additional data on the risks and benefits will assist the Agency in determining whether or not to cancel the pesticide, he may issue a notice of intent to hold a hearing pursuant to section 6(b)(2) of FIFRA to determine whether the registration should be cancelled or applications for registration denied. In the present instance, relative to the orchard, sugarcane, rice, rangeland, and other non-suspended uses of silvex, a determination to issue a notice of intent to hold a hearing pursuant to section 6 (b) (2) is the prudent course of action.

The foregoing review indicates that exposure to silvex and/or TCDD may result in significant adverse effects on exposed populations. Agency analysis shows that the rice, sugarcane, orchard, rangeland and non-crop uses of silvex create opportunities for direct and indirect exposure to humans through aerial drift and/or related contamination of water, food, and environmental media. Even without quantitative data[*/] on levels and routes of exposure, it is clear that any exposure, particularly in the case of TCDD, whether from a single source or cumulative sources, appears to pose risks of oncogenic, fetotoxic and/or teratogenic effects in the exposed populations. Additional data on routes of exposure, relative contribution from the several uses of the pesticide in areas of multiple use, and mechanisms for reducing exposure would assist the Agency in assessing with greater precision the degree of hazard associated with the non-suspended uses of silvex.

[*/] Because of the many varied and widespread uses of silvex silvex, it is often difficult, or impossible, to ascribe residue to any one particular use.

The Agency estimates that cancelling the use of silvex on range would have only a slight impact on farm income and beef prices. A number of chemical and non-chemical alternatives to silvex are available to control the various weeds not treated with silvex. The availability of alternatives and the very small quantity of acreage involved indicate that no unreasonable economic impacts will be felt at either the consumer or market levels if silvex is cancelled for this use. At the user level, some increased control costs and decreased production may be experienced by a small number of users. In some locations, the impact on users may be significant.

There are several chemical alternatives which are likely to be employed as substitutes for silvex use on rice. These compounds may be somewhat less effective and/or more expensive than silvex for use on some weeds. Therefore, some degree of increased control costs and reduced production may be experienced on some acres as a result of the substitution of these materials for silvex. At the user level the increased costs and reduced production will not be large. However, because silvex is used on little rice-growing acreage, the economic impact at the user, the consumer and market levels will be quite small if silvex were cancelled for this use.

NAA (1-Napthnleneactic acid) and Alar (Succinic acid 2,2-dimethyl hydrazine) probably would be used by apple growers as chemical alternatives to silvex. Some acres would require two annual treatments with these materials for effective control, whereas use of silvex requires only one treatment. The economic impact is likely to consist of higher costs to apple growers resulting from the use of these alternatives equivalent to a total of approximately $1 million per year or $20 per average affected acre. The higher drop control costs will increase production costs by 2-3% per year. Apple production and quality should not be significantly affected. Prune growers currently using silvex would suffer significant income reductions if silvex is unavailable. Italian and early Italian prunes in the Northwest states drop an average of 35% of the fruit if silvex is not applied in mid-June to control summer drop. Since there are no registered alternatives to silvex, production and revenues would decline sharply on the affected acres. Revenue reductions totaling $1.8 million annually, or $222 per affected acre, are projected to occur, assuming no alternatives to silvex are developed to prevent preharvest drop. Continued losses of this magnitude would eventually cause growers to push out the estimated 8,300 acres of prunes for which preharvest drop problems are significant.

The retail price of apples and pears would be unaffected by cancellation of silvex for orchard use. The retail price of prunes would increase by an undetermined amount.

The dicamba - 2,4-D combination alternative is likely to be the most commonly used substitute if silvex is cancelled for use on sugarcane. Economic impacts arising from a cancellation of silvex would result from reduced yield, which would occur because the alternative is less effective than silvex. A worst-case estimate indicates a 2% loss of overall U.S. sugarcane production could be experienced. Since U.S. produced cane sugar comprises only 18% of the total U.S. sugar supply, no measurable sugar price changes are likely to occur at either the market or consumer levels.

Both chemical and non-chemical controls are available as alternatives to silvex for use on non-crop areas. The chemical alternatives include 2,4-D, picloram, dicamba, AMS, amitrole. Non-chemical controls include mechanical methods such as mowing, shearing, and manual methods. The relative efficacy of the alternatives in comparsion to silvex is unknown. However, it is believed that one or a combination of the chemical alternatives will be widely substituted for silvex and will provide equivalent control.

The economic impact of cancelling silvex for non-crop uses is not likely to be significant at user, consumer or market levels; little acreage is treated with silvex, and effective alternatives are readily available. In addition, weed control on these acres does not confer significant economic benefits.

While the benefits of silvex use on rangeland, rice, sugarcane, orchards and non-crop areas are in some respects not insubstantial, these benefits do not, in the Agency's judgement, appear to offset the risks which these uses pose to man and the environment. Accordingly, the rangeland, rice, sugarcane, orchard and non-crop uses of silvex appear generally to cause unreasonable adverse effects on the environment.

Because of uncertainties and incomplete data relating to some of the factors which enter into the risk-benefit analysis, the Agency is seeking additional data on these silvex uses before making a final regulatory determination. FIFRA provides for the resolution of such questions through public hearings held pursuant to section 6 (b)(2). Through the hearing process, the uncertain areas become subject to public debate, new information is collected, and the Agency is able to arrive at an informed decision.

Moreover, in this case, a section 6(b)(2) hearing is particularly appropriate because section 6(b)(1) hearings on the suspended uses of silvex are currently in progress. Because many of the issues to be reviewed and resolved are generic to both the suspended and the non-suspended silvex uses, information and approaches developed for one category may shed additional light on the other category. Thus, a section 6(b)(2) hearing merged with the ongoing 6(b)(1) hearing would allow consolidated debate and disposition regarding all silvex uses.

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Memo. 1979b. TADP review at University of Wisconsin, TCDD in rats, dated February 8, 1979. From H.W. Spencer and W. Woodrow to D. Reisa and H. Warnick.

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